Feb. 21, 1967 S. POLANSKY 3,304,557

SURGICAL PROSTHESIS

Filed Sept. 28, 1965 2 Sheets-Sheet 1

Fig. 1.

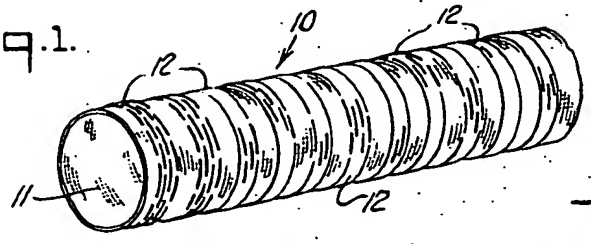


Fig. 2.

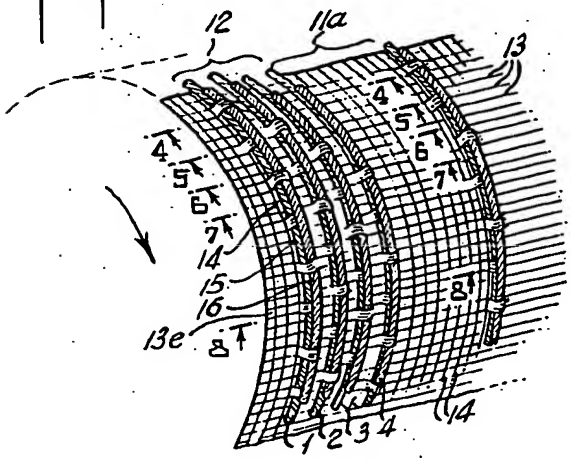


Fig. 3.

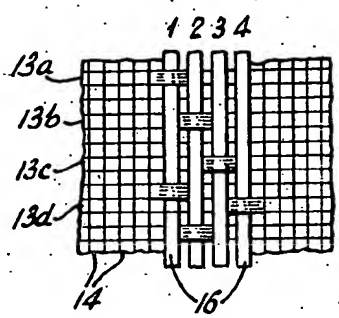


Fig. 4.

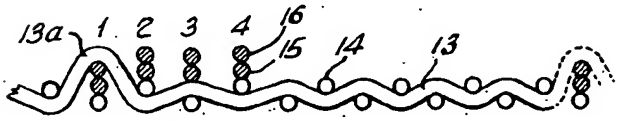


Fig. 5.

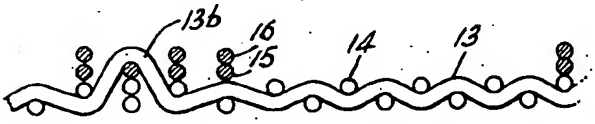


Fig. 6.

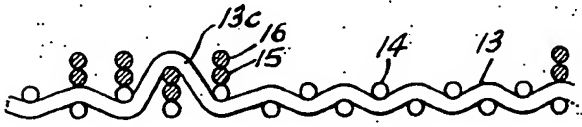
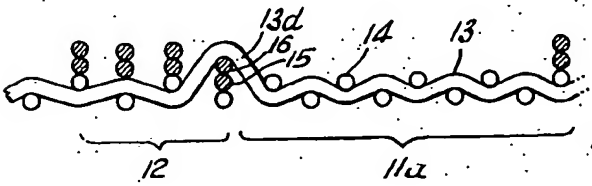


Fig. 7.



INVENTOR.
SEYMOUR POLANSKY

Flynn, Thorn & Jangarathis
ATTORNEY

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SURGICAL PROSTHESIS

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Fig. 8.

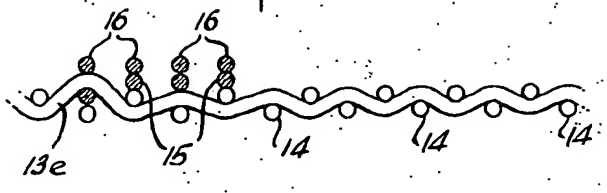


Fig. 9.

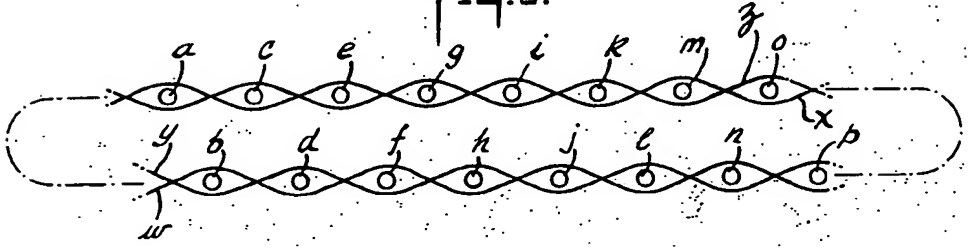


Fig. 10.

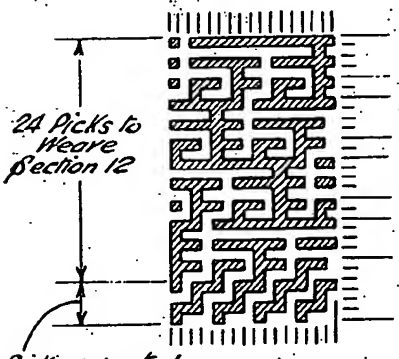
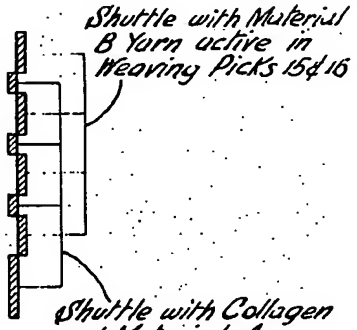


Fig. 11.



INVENTOR
SEYMOUR POLANSKY
BY Fleyen, Mann & Jangarian
ATTORNEY

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United States Patent Office 3,304,557 Patented Feb. 21, 1967

3,304,557

SURGICAL PROSTHESIS

Seymour Polansky, Riverside, Conn., assignor to Ethicon, Inc., Somerville, N.J., a corporation of New Jersey

Filed Sept. 28, 1965, Ser. No. 502,801
16 Claims. (Cl. 3—1)

The present application is a continuation-in-part of my earlier filed copending applications Serial No. 246,002 filed December 20, 1962, now abandoned, and Serial No. 267,083 filed March 22, 1963 (now abandoned).

This invention relates to prostheses requiring support to maintain an open lumen when placed in an animal body, particularly in the human body. More particularly, the invention has to do with artificial parts for an animal body.

During the past decade, considerable attention has been given to development of artificial vascular parts or grafts as implants for animal bodies. Synthetics such as Vinyon-N, nylon, Orlon, Dacron, Teflon and Ivalon have been woven and knitted into tubes and other suitable shapes, for use as arteries, veins, ducts, esophagi and the like. It has been recognized that an artificial graft must meet a number of standards in order to be of value. In particular, the graft must have certain physical properties such that it can be readily handled and manipulated during the specific surgery calling for its use. It must be flexible, for such is essential during an operation when time is critical and the graft must be accommodated to the artery, vein or the like to which it is being secured. It is sometimes necessary in surgery to bend a device or graft either around or under a body organ. An essential feature is that the graft be sufficiently rigid, though bendable, to allow for flexing without collapse and closing of the lumen thereof. If the graft does not have such strength, there is ever present the danger that when bent or flexed acutely in the body the lumen would collapse, leading to fatality.

It has also been recognized that a suitable prosthesis for the body should be non-toxic, flexible and porous. The ideal prosthesis should retain its strength permanently in intimate contact with the body fluids and should be readily accepted and incorporated into the tissues. Porosity is an important characteristic of such a prosthesis to avoid the formation of fluid pockets and to promote the growth through the fabric of repair tissue. Proper merging of the fabric with the body structure is also essential.

It is an object of this invention to provide flexible implants in the form of a tube comprising an association of collagen and a non-absorbable material wherein collagen and a non-absorbable material, in the form of a reinforcement, are integrated according to a predetermined pattern. A further object is to provide a tube in which a non-absorbable material is integrated in the form of a pattern adjacent the outer surface only of the tube to provide mechanical support therefor. Still another object is to form artificial vascular parts for an animal body suitable for use as arteries, veins, ducts, esophagi, trachea, or the like, the parts having desired porosity and being free from kinking or collapsing in any desired diameter or length. Still other objects of the invention will appear from the following description.

The foregoing objects are realized by providing an article of cylindrical tube shape comprising an association of collagen and a non-absorbable material A having integrated therewith a non-absorbable material B. Material

B is integrated in a patterned arrangement with an association of collagen and material A to provide mechanical support. Particularly preferred, however, is an article wherein material B is so integrated upon the outer surface only of the tube as to provide mechanical support for said tube. As used herein, the term "integrated" means that material B is actually incorporated into the structure of the tube, as by weaving, such that material B is established as an integral and patterned portion of the tube. As pointed out hereinafter in more detail, materials A and B can be the same or different.

A better understanding of the invention may be had from the following description read in conjunction with the accompanying drawings in which:

FIGURE 1 is a perspective view of a reinforced collagen-containing tube embodying the invention;

FIG. 2 is a diagrammatic perspective view, somewhat enlarged, of a portion of the tube shown in FIG. 1;

FIG. 3 is a planar development of a portion of the surface of FIG. 2;

FIGS. 4, 5, 6, 7, and 8 are, respectively, longitudinal sectional views on lines 4—4, 5—5, 6—6, 7—7, and 8—8 of FIG. 2 looking in the direction of the arrows shown in the last-mentioned figure;

FIG. 9 is a diagrammatic view illustrating the manner in which the body portion of the collagen-containing tube can be woven, it being understood that the selvedged edges of the woven member complete the tube as indicated by dotted lines;

FIG. 10 is a weave pattern for a tube embodying the present invention; and

FIG. 11 indicates diagrammatically the shuttles which are active in weaving the various picks in accordance with the pattern of FIG. 10.

Collagen used herein can be prepared as described in United States Patent No. 2,920,000 of H. R. Hochstadt and E. R. Lieberman. The preparation of a collagen multifilament suitable for use is described in copending application Serial No. 216,247, filed August 10, 1962, and Example XII of U.S. Patent No. 3,114,372.

The artificial vascular parts or tubes contemplated herein, comprise collagen filaments associated with filaments of a non-absorbable material which has been designated as "material A." Material A is not absorbed by an animal body, such as the human body, when present therein over extended time intervals (e.g., a decade). Material A can be natural or synthetic. Examples of suitable materials from which such filaments can be made are: Vinyon-N, a resin manufactured by the Carbide & Carbon Corporation, by copolymerizing vinyl chloride and acrylonitrile; Saran, a vinyl chloride polymer manufactured by the Dow Chemical Company; nylon, a polyamide resin made by polymerization of the hexamethylene diamine salt of adipic acid; Orlon, a synthetic fiber made from polyacrylonitrile; Dacron, a synthetic fiber made from terephthalic acid and ethylene glycol; Teflon, a tetrofluoroethylene polymer; polyolefins such as polyethylene and polypropylene. Nylon, Orlon, Dacron, and Teflon are products of the E. I. du Pont de Nemours & Co. Preferred herein are Dacron, Teflon and polyolefins.

The filaments of non-absorbable material B is integrated as a reinforcing element with a collagen-non-absorbable material A tube, can be the same as material A or can be different. In general, material B is the same as material A and is one of those given above under the designation "material A." In the event that material B

differs from material A, it is also taken from the same group of materials identified by the designation "material A."

In the embodiment of the invention illustrated in the several figures, there is provided a woven tube 10 having a main or body portion 11 extending throughout its length with a series of reinforcing ring sections 12 spaced along the tube adjacent its outer surface and forming an integral part thereof. The tube comprises warp yarns 13 which are multifilaments made of mixtures of collagen filaments and filaments of any other material A heretofore suggested. Appropriate percentages of the respective filaments desirably included in each of the yarns are set forth in examples to follow.

The tube in its main or body portion has weft yarns or picks 14 which can be the same as those used in the warp or which can possess different percentages of collagen filaments and other filaments of material A depending upon the characteristics desired to be built into the implant. The tube in its reinforcing ring sections 12 comprises additional picks or weft yarns 15 and 16 of material B integrated into the weave and which serve to prevent it from kinking or collapsing even when repeatedly flexed. The picks 15 and 16 of material B can be multifilaments or monofilaments, preferably the latter and preferably heavier than the warp or the other weft threads and of a size dependent upon the strength desired to be built into the implant. These reinforcing picks (15 and 16) can be made of a non-absorbable material B which can be the same as the non-absorbable material A incorporated in those yarns which include the collagen or they can be made of a different non-absorbable material as previously pointed out.

Between the ring sections 12 of the tube there are body sections 11*a* in which each pick 14 weaves above alternate warp yarns and below intervening warp yarns. In the ring sections 12 per se, the picks are arranged in four groups 1, 2, 3, and 4, of three picks each of which one pick in each group, i.e., the inner pick 14 preferably is woven of the same yarn as in the body sections 11*a* between ring sections, and with the same type of weave, i.e., above alternate warp yarns and below intervening warp yarns (FIG. 2). The picks 14 in the ring sections lie in the same cylindrical surface as the picks 14 in the body sections 11*a* of the tube between ring sections. Adjacent the outer surface of the tube there is in each group of picks in the ring sections, a pick of the reinforcing material which floats over three warp yarns and passes beneath each fourth warp yarn, and a pick 16 of reinforcing material which overlies pick 15 and which floats over seven warp yarns beneath each eighth warp yarn. The underlying floater yarns 15 in each group pass under the same warp yarns as do the overlying floater yarns 16 in such group, but the underlying floaters pass beneath additional warp yarns which are located intermediate those under which the overlying floater yarns pass.

In each ring section and as between the groups 1, 2, 3, and 4, the overlying floater picks 16 of the respective groups pass beneath warp yarns spaced three away in the circumferential direction of the large arrow (FIG. 2) from the warp yarns under which pass the overlying floater of the group next to the left. Thus, in the section of FIG. 4, warp yarn 13*a* passes over both floaters in leftmost group 1. In the section of FIG. 5, warp yarn 13*b* is spaced three warp yarns away from warp yarn 13*a* and likewise passes over both floaters 15 and 16 in group 2. In the section of FIG. 6, warp yarn 13*c* is spaced three yarns away from warp yarns 13*b* and overlies picks 15 and 16 in group 3. And in the section of FIG. 7, warp yarn 13*d* is spaced three warp yarns away from warp yarn 13*c* and overlies picks 15 and 16 in group 4. This arrangement is repeated in the respective groups every eighth warp yarn around the tube in the direction of the arrow.

In the section shown in FIG. 8, warp yarn 13*e* passes over the underlying pick 15 in group 1 and under the overlying pick 16 in that group. This pattern is repeated at spaced intervals of eight warp yarns in the circumferential direction of the arrow as regards each group and at spaced intervals of three warp yarns in the direction of the arrow as between the respective groups 1, 2, 3, and 4 in each ring section.

With a weave pattern of the type just described, the inner wall of the body portion of the tube comprising warp yarns 13 and picks 14 is substantially uniform through out its length and devoid of ridges or prominent protuberances as might lessen the efficiency of flow within the tube in an animal body. The picks 15 and 16 comprising the floaters of the ring sections 12 and which supply the necessary rigidity in the tube are integrated into the weave of the ring sections but only adjacent the outer surface of the tube.

A weave pattern which results in a woven tube of the type heretofore referred to is shown in FIG. 10. This pattern from left to right covers a series of sixteen warp yarns and is repeated thoughout each adjacent group of sixteen warp yarns. The pattern also includes from top to bottom a series of twenty-four picks constituting the ring sections 12 of the tube and a series of sixteen picks constituting the body sections 11*a* of the tube. Insofar as the actual wall of the tube is concerned, however, as distinguished from the manner in which it is woven, this pattern reflects a series of twelve picks comprising the groups 1, 2, 3, and 4, in the ring sections 12 of the tube and a series of eight picks in the body sections 11*a* of the tube. The reason for this is that the tube is woven flat and the weave pattern is such that the loom shuttle, as it travels in one direction, cooperates with different groups of warp yarns from those it cooperates with on the return stroke of the shuttle. In that portion of the pattern which corresponds to the body portion 11*a* of the tube, four picks are laid down before the weave pattern is repeated. In the pattern, the shaded squares represent a condition where the warp overlies the pick during the shuttle travel and the unshaded squares a condition where the pick overlies the warp during shuttle travel. The type of fabric formed from this pattern in the body portion 11*a* of the tube is exemplified in Example I and in FIG. 9 where "over" and "under" indicates the location of the warp with respect to the pick, "*l* to *r*" and "*r* to *l*" (i.e., left to right and right to left, respectively) the direction of shuttle movement; and the letters *a* to *p* of the alphabet indicate the designation of warp yarns, which in FIG. 9 are illustrated diagrammatically with alternate warp yarns at different levels, as an aid to understanding.

Example I

	Over									
	Under									
l to r Pick w		a	b	c,d,e	f	g,h,i	j	k,l,m	n	o,p
r to l Pick x	a,b	c	d,e,f	g	h,i,j	k	l,m,n	o	p	
l to r Pick y		a,b,c	d	e,f,g	h	i,j,k	l	m,n,o	p	
r to l Pick z		a	b,c,d	e	f,g,h	i	j,k,l	m	n,o,p	

The shuttle in laying pick *w* in each repeat pattern represented by FIG. 9 travels first under warp yarn *a* located in the top level, and then over warp yarn *b*, in the lower level. Thereafter, the shuttle passes under groups of three warp yarns *c–d–e*, *g–h–i*, and *k–l–m*, of which two warp yarns are located in the top row and one warp yarn on the bottom row, and over other single warp yarns *f–j–n*. On the return stroke, reading from right to left, the shuttle in laying down pick *x* passes first over warp yarn *p* located on the bottom row, then under warp yarn *o* located in the top row, then over the next three warp yarns *n–m–l* located two in the bottom row and one in the top row and, continuing on the return throw, under warp yarns *k–g–c* in the top row and over groups of warp yarns *j–i–h*, *f–e–d* and *b*, located in accordance with the pattern, two in the bottom row and one in the top row except for *b*.

In laying down the third pick *y*, the shuttle, in accordance with the pattern, travels from left to right under the groups of warp yarns *a–b–c*, *e–f–g*, *i–j–k* and *m–n–o* located two in the top row and one in the bottom row, and over warp yarns *d–h–l–p* located in the bottom row. And again on its return stroke from right to left, in accordance with the pattern, the shuttle in laying down pick *z* passes over groups of warp yarns *p–o–n*, *l–k–j*, *h–g–f*, and *d–c–b* located two in the bottom row and one in the top row, and under warp yarns *m–i–e–a*.

In accordance with that pattern, two distinct layers of fabric are woven which are joined together at the selvedge edges with each pick in the respective layers passing over alternate warp yarns and under intervening warp yarns, and with adjacent picks in said layers passing over the intervening yarns and under the alternate yarns. Such a woven fabric can be blocked into a cylinder.

With this explanation, one skilled in the art can readily weave the pattern of reinforcing floater picks illustrated in FIGS. 1 to 3, by following the diagram illustrated in FIG. 10. In this connection it is to be noted that the yarn for picks 14, constituting the body portion of the tube, is carried by one shuttle while the yarn for the reinforcing picks 15 and 16 is carried by a different shuttle (FIG. 11), the loom being provided with a plurality of boxes at each side to receive the different shuttles and which can be selectively brought into operative position as demanded by the pattern. Again, with reference to the pattern shown in FIG. 10, in each group of picks 14, 15 and 16, that pick which has the greatest degree of float is laid down first, namely, the pick 16 corresponding to the top row in the pattern as the shuttle travels from left to right and the second row of the pattern as the shuttle returns from right to left. Thereafter, during the next four throws of the shuttle, the take-up of the loom is stopped in order to obtain the appropriate overlying and underlying relationship for the other picks 14 and 15 in the group. In other words, out of each six throws of the shuttle (four to lay down the reinforcing picks 15 and 16 and the two picks 14 in the body portion of the tube) the take-up of the loom is stopped on the third, fourth, fifth, and sixth throws of the shuttle.

It will be understood, of course, that many variations in weaving pattern can be made using the same combination of yarns and with different combinations of yarns, all in order to carry out the general scheme of the invention which contemplates the integration of a general pattern of reinforcing elements into a tube but adjacent only the outer surface thereof. For example, instead of the annular ring configuration shown in FIG. 1, the reinforcement can be in the form of a helix, alternating rings and helix, double helixes, half-loops, etc.

Material A is used in the form of multifilament yarns, and material B is used in the form of monofilament yarns. Depending upon the requirements of the implant, desired rigidity thereof can be achieved by a "heat-setting" treatment. Multifilament yarns and low gauge monofilament yarns are generally heat-set. While heavier gauge monofilaments do not generally require "heat-setting" to provide approximately the same rigidity, it is preferable to heat-set. A tube can be heat-set when it is placed on a mandrel or rod which has an external diameter slightly less than that of the tube. The tube with mandrel inserted therethrough is then heated to a temperature from about 100° C. to 170° C. for approximately 20–5 minutes, during which time the tube is heat-set; that is, it assumes a substantially rigid configuration. It is to be understood that conditions of temperature and time will vary with the character of materials A and B and the quantity of collagen present; however, the conditions selected will fall within the range given.

Approximate percentage ranges by weight of collagen and materials A and B used herein, are as follows: collagen, 10 to 90; material A, 5 to 45; and material B, 5 to 45.

It is to be understood that any tanning agent for collagen can be used herein. Chromium, formaldehyde, polyhydroxyphenols, etc. can be used alone or in combination.

The present invention is more fully described and exemplified in the following examples and related discussion. It is to be understood, however, that the invention is not to be limited to any specific form of materials or conditions set forth in the examples, but is limited solely by the description in this specification and appended claims. Throughout the specification and all examples provided herein, all quantities are expressed in parts by weight unless otherwise specified.

Example II

In this example, a tube is formed of collagen and of Dacron, with annular rings being formed of polypropylene. The tube is woven in accordance with the pattern of FIGS. 10 and 11. One shutter of the loom carries a mixed collagen-Dacron multifilament; the second shuttle of the loom carries a polypropylene monofilament. Specifications of the tube and annular rings thereof, are:

Weave—50 picks per inch;
Warp—440 denier collagen and 140 denier Dacron, 2 ply, 2.5 turns per inch, 291 ends;
Filling—same as warp;
Ring—14.5 mil polypropylene monofilament, spacing between rings 5/32", width of ring 3/16".

Example III

The same warp and background filling is used as in Example II. Monofilament Saran (14 mils) is used in the second shuttle. The spacing between rings is 3/16 inch. After weaving, the tube is "heat-set" for 20 minutes at 160° C. on a mandrel. The tube is then removed from the mandrel. Digestion with 1% aqueous trypsin solution at 7.4 pH shows that fabric skeleton is rigid radially and exhibits some longitudinal flexibility.

Example IV

Again, the same warp and background filling is used as in Example II. The annular ring supporting structure is made by using 18 mil Kynar (Teflon) monofilament. By simply rolling the tube repeatedly by hand, the lumen thereof is opened after digestion with trypsin. The rigidity of the tube is at least as great as that of Example III, and also exhibits an ability to be bent without collapse of the lumen and to open and close in accordion fashion.

Example V

The same warp and background filling—collagen and Dacron—is used as in Example II. The annular ring reinforcing structure is made using 14 mil polypropylene monofilament (picks 15 and 16). The rings are 5/32 inch

apart and 3/16 inch wide. The device is "set" on a mandrel at 160° C. for 20 minutes. This device, and several similar devices, have been implanted in dogs. All have remained patent during 4 month periods.

Example VI

A tube crimped on a mandrel was held in an autoclave for 12 minutes. The pressure in the autoclave was about 12 p.s.i.

In this example, a 6 inch tube was used. The tube had a diameter of 10 mms. and the mandrel upon which it was crimped had a diameter of about 9 mms.

The tube was a plain weave (one up and one down) of Dacron and collagen yarn. Collagen multifilament yarn, 190 denier, 18 ends (7½Z) and Dacron multifilament yarn, 70 denier, 34 ends (5Z) are twisted together (1 turn S ply) and used for the warp and filling. The tube is woven using a reed 28, 5 ends per dent, with 97 warp yarns and 70 picks per inch.

The tube was used for a thoracic implant in a dog. The implant continues to function after 7 months in the animal.

Example VII

A tube (identical to the one in Example VI) crimped on a mandrel was immersed in a large excess of water, at a temperature of 50° C. for 5 minutes, and was then dried. The tube was removed from the mandrel. When rewet with water, the tube lost very little elasticity and, when bent acutely, an open lumen was maintained. These characteristics were exhibited satisfactorily after several wetting and drying cycles.

Example VIII

A tube (identical to the one in Example VI) crimped on a mandrel was treated with a large excess of an aqueous tanning solution comprising 1 part of formaldehyde, chromium sulfate equivalent to 0.4 part of chromic oxide, followed by a solution of 0.5 part of pyrogallol and 0.6 part of $Na_2S_2O_4$. The tube was then dried and the mandrel removed therefrom. The characteristics of the tube were similar to those of the crimped tube obtained in Example VII.

An advantageous feature of setting the tube in crimped configuration by this tanning technique is avoidance of any collagen degradation. There is no need to heat the tube during the tanning procedure.

A 2 inch sample of this tube was stretched to 2½ inches and was implanted as an abdominal graft in a dog. The surgical procedure was without incident. The graft remains patent after three months.

It is to be understood that any of the known tanning agents for use with collagen can be used herein. Chromium, formaldehyde, polyhydroxyphenols, etc. can be used alone or in combination. Particularly preferred herein, however, are the tanning procedures described in United States Patents Nos. 3,166,073 and 3,1660,074.

As indicated above the articles formed as described herein are useful as tubular grafts. They have desired characteristics as revealed by their maneuverability, flexing quality and capability of maintaining an open lumen when flexed. In addition, they have the desired feature of porosity, as well as integrating well with body tissue.

While the invention has been described in detail according to the preferred method of carrying out the process and yielding the products, it will be obvious to those skilled in the art, that changes and modifications can be made (without departing from the spirit or scope of the invention) and it is intended in the appended claims to cover such changes and modifications.

What is claimed is:

1. As a surgical prosthesis comprising, a tube having a wall fabricated of threads of collagen absorbable in live animal tissue and threads of other material non-absorbable in live animal tissue, and reinforcing means located essentially on the outer surface of said tube and spaced intermittently along the longitudinal axis thereof, said reinforcing means comprising non-absorbable threads circumferentially positioned around said tube perpendicular to said longitudinal axis.

2. A surgical prosthesis, comprising:

a woven tube of multifilament yarn, said yarn containing collagen filaments and non-absorbable filaments; and,

a non-absorbable monofilament located essentially on the outer surface of said tube and spaced intermittently along the longitudinal axis thereof, said monofilament being circumferentially positioned around said tube perpendicular to said longitudinal axis.

3. A surgical prosthesis, comprising:

a woven tube of multifilament yarn, said yarn containing collagen filaments and non-absorbable filaments; and,

a non-absorbable multifilament yarn located essentially on the outer surface of said tube and spaced intermittently along the longitudinal axis thereof, said multifilament yarn being circumferentially positioned around said tube perpendicular to said longitudinal axis.

4. The surgical prosthesis of claim 2 wherein the monofilament is patternly woven into the outer surface only of said tube to provide mechanical support therefor.

5. The surgical prosthesis of claim 2 wherein the monofilament is a terephthalic acid ethylene glycol ester fiber.

6. The surgical prosthesis of claim 2 wherein the monofilament is a tetrafluoroethylene polymer.

7. The surgical prosthesis of claim 2 wherein the monofilament is a polyethylene polymer.

8. The surgical prosthesis of claim 2 wherein the monofilament is a polypropylene polymer.

9. A surgical prosthesis, comprising:

a tube woven of warp yarns containing collagen filaments and non-absorbable filaments and weft yarns of collagen filaments and non-absorbable filaments; and,

non-absorbable monofilaments being integrated in a series of annular rings spaced intermittently on the outer surface only of said tube perpendicular to the longitudinal axis thereof thereby providing mechanical support for said tube.

10. The surgical prosthesis of claim 9 wherein the monofilament that forms said annular rings has the same composition as the non-absorbable filaments that are present in the warp yarns of the tube.

11. The surgical prosthesis of claim 9 wherein the monofilament that forms said annular rings has a different composition than the non-absorbable filaments that are present in the warp yarns of the tube.

12. The surgical prosthesis of claim 9 wherein the non-absorbable filaments in the warp yarns and the non-absorbable filaments integrated in a series of annular rings on the outer surface of said tube are terephthalic acid ethylene glycol ester filaments.

13. The surgical prosthesis of claim 9 wherein the non-absorbable filaments in the warp yarns and the non-absorbable filaments integrated in a series of annular rings on the outer surface of said tube are tetrafluoroethylene filaments.

14. The surgical prosthesis of claim 9 wherein the warp and weft yarns contain from 10% to 90% collagen filaments and from 10% to 90% non-absorbable filaments.

15. The surgical prosthesis of claim 9 wherein said tube is wholly constructed of a single multifilament yarn, said yarn being characterized by the presence therein of about 2.5 parts by weight collagen monofilaments and

about 1 part by weight of non-absorbable monofilaments.

16. The prosthesis of claim 15 in a permanently crimped condition.

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RICHARD A. GAUDET, *Primary Examiner.*

DALTON L. TRULUCK, *Examiner.*

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United States Patent [19]

Schmitt

[11] Patent Number: 5,509,931

[45] Date of Patent: Apr. 23, 1996

[54] **RAVEL-RESISTANT SELF-SUPPORTING WOVEN VASCULAR GRAFT**

[75] Inventor: **Peter J. Schmitt**, Garnerville, N.Y.

[73] Assignee: **Meadox Medicals, Inc.**, Oakland, N.J.

[21] Appl. No.: **188,560**

[22] Filed: **Jan. 28, 1994**

Related U.S. Application Data

[60] Continuation of Ser. No. 875,876, Apr. 29, 1992, Pat. No. 5,282,846, which is a division of Ser. No. 573,947, Aug. 28, 1990, abandoned.

[51] **Int. Cl.**[6] **A61F 2/06**

[52] **U.S. Cl.** **623/1**; 623/12

[58] **Field of Search** 623/1, 11, 12; 606/194, 198, 153; 600/36; 604/8

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Primary Examiner—Debra S. Brittingham
Attorney, Agent, or Firm—Hoffmann & Baron

[57] **ABSTRACT**

A ravel-resistant, self-supporting woven synthetic fabric vascular graft including a fusible fiber integrated into the weave in the filling yarn is provided. The graft is woven from multifilament polyester warp yarns which can be textured or flat. The filling yarn includes a low melting fusible fiber or resin which can be combined with a stiff monofilament. The monofilament component provides radial rigidity to improve kink and crush resistance. After heat setting, the low melting fusible resin fuses to orthogonal warp yarns at each intersection and provides ravel resistance to the finished graft. Improved kink resistance make the tubular grafts suitable for use in medium and small diameter peripheral applications. A preferred graft has a single velour outer surface and a smooth inner surface.

27 Claims, 1 Drawing Sheet

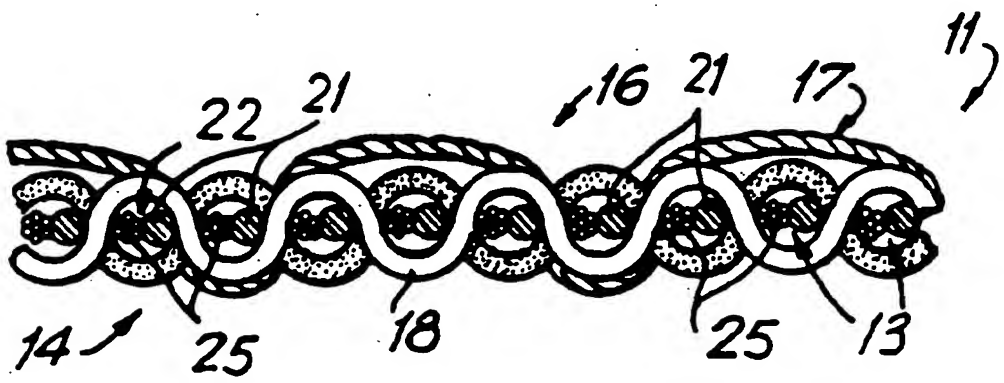
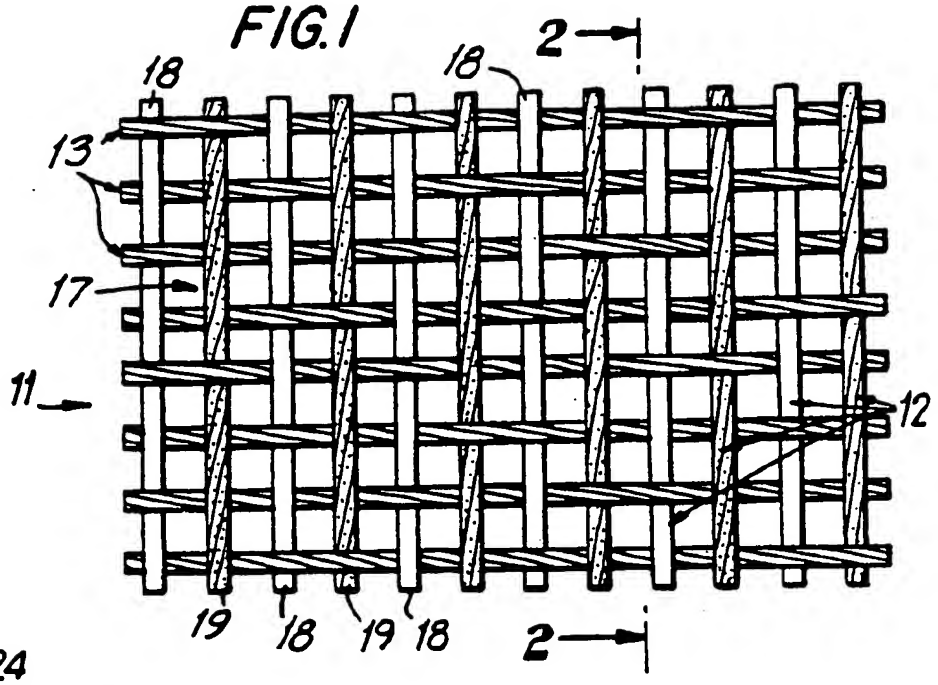


FIG. 1



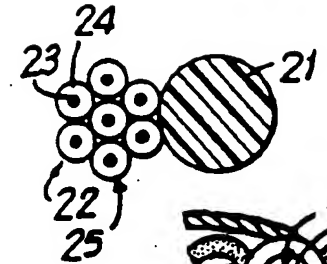


FIG. 3

FIG. 2

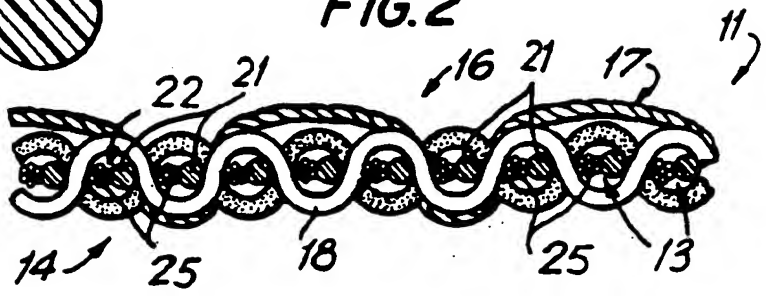


FIG. 5

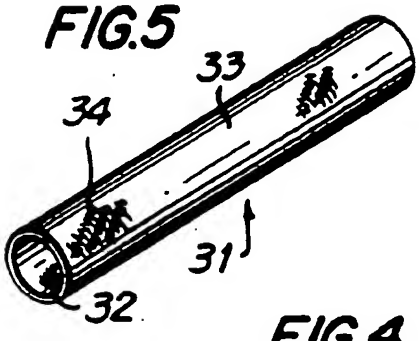


FIG. 4

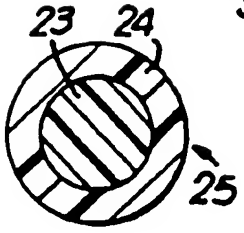
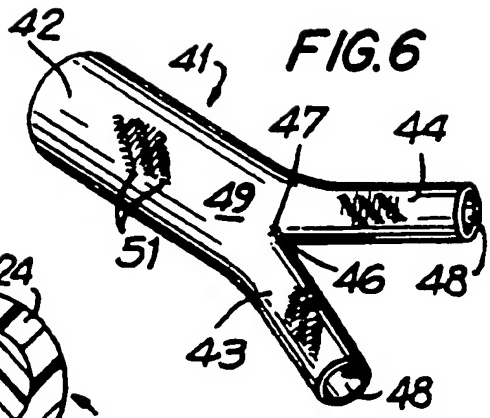


FIG. 6



RAVEL-RESISTANT SELF-SUPPORTING WOVEN VASCULAR GRAFT

This is a continuation of application Ser. No. 07/875,876 filed Apr. 29, 1992, now U.S. Pat. No. 5,282,846 issued on Feb. 1, 1994 which is a divisional of application Ser. No. 07/573,947 filed on Aug. 28, 1990, and now abandoned.

BACKGROUND OF THE INVENTION

This invention relates to synthetic vascular grafts, and more particularly to synthetic woven vascular grafts which are ravel-resistant due to inclusion of a fusible component and self-supporting due to inclusion of a stiffening component.

Vascular grafts of synthetic materials are widely used for the replacement of segments of human blood vessels. Synthetic vascular grafts have taken a wide variety of configurations and are formed of a wide variety of materials. Among the accepted and successful vascular graft implants are those formed from a biologically compatible material in tubular form which retain an open lumen to permit blood to flow normally through the graft after implantation. The biologically compatible materials include thermoplastic materials such as polyester, polytetrafluoroethylene (PTFE), silicone and polyurethanes. The most widely used are polyester fibers and PTFE. The polyester fibers, usually Dacron, may be knit or woven and may be of a monofilament, or multifilament, or staple yarn, or combination of each.

There are a wide variety of synthetic vascular grafts presently in use. An important factor in the selection of a particular graft is the porosity of the substrate of which the graft is formed and the strength requirements for the implant. Porosity is significant, because it controls the tendency to hemorrhage during and after implantation and influences ingrowth of tissue into the wall of the graft.

Synthetic fabric vascular grafts may be of a woven, knit or velour construction. A synthetic vascular graft having a warp-knit construction is disclosed by William J. Liebig in U.S. Pat. No. 3,945,052. Another graft having a warp knit double-velour construction is described by Liebig and German Rodriquez in U.S. Pat. No. 4,047,252. William J. Liebig and Dennis Cummings describe a synthetic woven double-velour graft in U.S. Pat. No. 4,517,687; the velour loops being formed of warp yarns which are texturized preshrunk multifilament yarns. These three issued United States patents for synthetic vascular grafts are assigned to the assignee of this application.

U.S. Pat. No. 4,892,539 issued to Durmus Koch describes a synthetic fabric woven graft with a single velour on the outer surface. The graft is described as woven from multifilament polyester yarns, specifically described as texturized, with the single outer velour formed of filling yarns with each velour loop extending outside a plurality of warp yarns.

After knitting or weaving the yarns into a tubular graft, the graft is compacted by a method such as disclosed in U.S. Pat. No. 3,853,462 to Ray E. Smith and No. 3,986,828 to Harmon Hoffman and Jacob Tolsma also assigned to the same assignee as this application. Compaction results in shrinking of the yarns in the fabric and generally reduces the overall porosity of the fabric substrate. These tubular grafts after compacting generally have a diameter from about 6 mm to 40 mm.

Subsequent to compacting, synthetic tubular fabric grafts are crimped. Crimping involves forming ridges in the wall of the grafts to eliminate the danger of kinking or collapse

of the tubing when flexed and results in uniform, regular, circular corrugations which provide uniform strength over the entire surface of the graft tubing. This applies to both the woven and knit fabric vascular grafts. Examples are shown by L. R. Sauvage in U.S. Pat. No. 3,878,565 who describes a tubular textile synthetic fiber prosthesis of a body having a multiplicity of outwardly extending fiber loops. In FIG. 2*a*, the graft body is crimped into irregular, circumferential corrugations. The degree of protection afforded by irregular corrugation varies over the lengths of the tube and can fall below the required level of protection at specific regions. The warp-knit and woven grafts described above in U.S. Pat. No. 3,945,052, No. 4,047,252 and No. 4,517,687 are circularly crimped. The graft in U.S. Pat. No. 4,892,539 is crimped in a spiral fashion. Crimped or corrugated walls can disrupt blood flow and create areas of thick tissue buildup, due to the profile.

S. Polansky in U.S. Pat. No. 3,304,557 avoids crimping in vascular prothesis by forming a tube with repeating reinforcing ring sections. These reinforcing ring sections incorporate reinforcing picks adjacent only the outer surface. He proposes that the annular rings can be in the form of a helix, alternating rings and helix-loops. These latter suggestions are similar to the tubular prosthesis of I. B. Medell in U.S. Pat. No. 3,479,670 wherein an open mesh tube is wrapped with two polypropylene monofilament right-hand and left-hand helices and fused to penetrate partially the exterior of the tube. In U.S. Pat. No. 3,272,204 to C. Artandi and L. D. Bechtol sew a Dacron fabric to Teflon rings or a helix to prevent an absorbable collagen reinforced graft tube from collapsing.

Selection of a particular type of graft substrate by a vascular surgeon depends upon several factors. Among the factors included is the particular location of the implantation. This also dictates the size of the graft in order to maintain a sufficiently large or small lumen to accommodate the normal blood flow in the region of implantation. The ultimate strength requirements and blood pressure in the location of implantation also affects the selection. Generally, the woven grafts provide greater strength and reduced porosity, but are generally considered to be more difficult to handle and suture and tend to unravel when cut, particularly at an oblique angle. Velours are often preferred because the velour surfaces facilitate growth of tissue into the loops extending from the surface of the velour fabric. The knitted grafts are generally softer and more easily sutured, but are generally more porous. Depending on the location of the implant and heparinization condition of the patient, synthetic fabric grafts generally must be preclotted with the patients blood before implantation. Preclotting may not be essential with a woven graft, but is generally recommended nonetheless.

Tubular grafts of smaller diameter, for example, 6 mm and below are often utilized in peripheral regions of the body and appendages. Today, the most successful in this respect are grafts of PTFE of the material disclosed by Robert W. Gore in U.S. Pat. No. 4,187,390 and No. 3,953,566. These grafts are formed by extrusion of the PTFE material. While accepted for use in small diameter applications, PTFE grafts often require surgical replacement within relatively short periods of time compared to the larger diameter fabric vascular grafts described above,

Accordingly, it is desirable to provide a synthetic fabric vascular graft suitable for a wide variety of dimensions and diameters providing the benefits of woven grafts, but do not tend to unravel when cut and which do not require crimping and will be self-supporting and maintain an open lumen,

SUMMARY OF THE INVENTION

Generally speaking, in accordance with the invention, a ravel-resistant, self-supporting woven synthetic vascular graft having improved kink resistance and incorporating fusible components into the weave are provided. A plurality of multifilament warp yarns and filling yarn are woven in tubular form and include a fusible component to prevent unravelling. The filling yarn may include a stiffening component to prevent collapse and provide a tubular graft of increased radial resiliency. The warp yarns may be the same as one another or include flat and texturized multifilament yarns. A filling of stiffer monofilament yarn and fusible components provide radial burst strength, dimensional stability and radial rigidity with resiliency to maintain the lumen of the tubular structure open and provide a sufficient degree of ravel resistance. The graft surface may be smooth or a single or a double velour.

In a preferred embodiment of the invention, the fusible component of the filling is a yarn formed from bicomponent fiber having a polyester core surrounded by a low melting temperature polymer sheath designed to bond to neighboring yarns to form a solid bond after exposure to heat. In another preferred embodiment, the ravel-resistant, self-supporting woven vascular graft has an exterior surface similar to a velour. The inner surface is provided with a fine, low profile woven surface to promote smooth, thin pseudointima formation. The loops on the exterior surface are formed of multifilament warp yarns which provide the necessary texture cover for tissue adhesion and ingrowth. The density of the multifilament warp yarns also controls blood porosity.

The woven grafts prepared in accordance with the invention are particularly well suited to 2–6 mm diameter peripheral vascular prosthesis, but are suitable for larger dimensions up to about 40 mm as well. Kink resistance is provided without the necessity to crimp the vascular graft.

Accordingly, it is an object of the invention to provide an improved woven synthetic vascular graft.

Another object of the invention is to provide a self-supporting woven synthetic vascular graft which is ravel-resistant.

A further object of the invention is to provide synthetic woven vascular graft which resists kinking without the need to crimp the graft.

A further object of the invention is to provide a woven synthetic fabric vascular graft which is suitable for peripheral use in small diameters of 6 mm or less.

Still another object of the invention is to provide a small diameter of woven synthetic fabric vascular graft which resists kinking and provides a desirable amount of longitudinal stretch without crimping.

Still a further object of the invention is to provide a ravel-resistant woven synthetic fabric vascular graft which includes an outer velour surface to promote tissue ingrowth.

Yet another object of the invention is to provide a self-supporting woven synthetic vascular graft having a fine, low profile woven surface to promote smooth, thin pseudointima formation.

Yet a further object of the invention is to provide a ravel-resistant woven synthetic fabric single-velour vascular graft having improved kink resistance without crimping.

Another object of the invention is to provide a method of preparing an improved ravel-resistant woven synthetic fabric vascular graft in accordance with the invention.

Still other objects and advantages of the invention will in part be obvious and will in part be apparent from the specification.

The invention accordingly comprises the several steps and the relation of one or more of such steps with respect to each of the others, the apparatus embodying features of construction, combination and arrangement of parts which are adapted to effect such steps, and the product which possesses the characteristics, properties, and relation of constituents (components), all as exemplified in the detailed disclosure hereinafter set forth, and the scope of the invention will be indicated in the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

For a fuller understanding of the invention, reference is had to the following description taken in connection with the accompanying drawing(s), in which:

FIG. 1 is a weaving diagram of a ravel-resistant woven synthetic fabric vascular graft prepared in accordance with a preferred embodiment of the invention;

FIG. 2 is a cross-sectional view in schematic in the warp direction a finished graft surface showing the interlacing ends and of the filling yarn of a graft fabric having the weave pattern of FIG. 1;

FIG. 3 is a cross-sectional view of an enhanced filling yarn of the graft substrate of FIG.

FIG. 4 is a cross-sectional view of a staple bicomponent fiber of the fusible component of the filling yarn of FIG. 3;

FIG. 5 is a perspective view of a tubular ravel-resistant woven single-velour vascular graft prepared in accordance with the invention; and

FIG. 6 is a perspective view of a bifurcated ravel-resistant woven single-velour vascular graft prepared in accordance with the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The woven synthetic vascular grafts prepared in accordance with the invention are applicable to a wide range of diameters, including the small 2 to 6 mm diameter range suitable for peripheral use as well as dimensions up to about 40 mm. Accordingly, the grafts may be woven having inside diameters which range from about 2 to about 40 mm are resistant to unravelling and are self-supporting and resist kinking without being crimped.

In a preferred embodiment of the invention, the woven graft has a diameter of 6 mm or less. In another preferred embodiment the woven graft has a exterior surface with loops and a smooth interior surface. The grafts are ravel-resistant, and are self-supporting and resistant to kinking without crimping the fabric surface. The grafts possess ravel-resistance imparted by heat setting warp and/or filling yarns which include fusible bicomponent staple fibers having a polyester resin core and low melting copolyester or polyethylene sheath. During heat setting the fusible resin sheath in the yarns in the woven fabric bond to each interlacing yarn in the weave. The fusible yarn is composed of Celbond Type K54 bicomponent staple fibers from Hoechst Celanese. The staple fibers are available 1½ to 3 inches in length and 2 to 15 denier. The yarns utilized are compatible biologically.

The stiffening component in the filling yarns may be a monofilament. Selection will vary depending on the desired characteristic of the tubular graft. However, the stiffening component must be sufficiently stiff to impart dimensional stability and radial rigidity to the tube without crimping. The

stiffening component should have the following minimum physical properties:

Tenacity ≧ 3 grams per denier Diameter: >2< 10 mils (53,000 psi)
Initial Modulus ≧ 50 grams/denier (800,000 psi)
$EI \geq 3.9 \times 10^{-6}$ lb. in^2

Where EI is the calculated bending stiffness, E is the modulus of elasticity, I is the moment of inertia

$$I = \frac{\pi r^4}{64}$$

The diameter m can vary depending on desired characteristics, but will typically be in the range of 2 to 10 mils.

The grafts possess longitudinal elasticity imparted by heat setting when the graft is longitudinally compressed. This compresses the warp yarns to impart the stretch without having to crimp the fabric surface.

Preferably, the majority of the yarns utilized in the woven graft are polyethylene terephthalate, such as Dacron polyester available from du Pont or polyester available from Teijin, Hoechst-Celanese and Toray Industries. The graft substrate is formed by weaving a plurality of warp ends of multifilament yarns with a combined filling yarn of fusible yarn and stiffer monofilament yarn which have been plied or wound together prior to weaving. The woven fabric is heat set to bond the bicomponent fibers to orthogonal warp yarns to provide longitudinal compliance which maintains integrity of the graft. The bonding of the low melting sheath of the bicomponent staple fibers to the interlacing warp yarns provide ravel-resistance. The plurality of bond sites allows the tubular graft to be cut at any angle and maintain ravel-resistance.

The monofilament polyester utilized as a stiffening component in the Example which follows is a 5 mil polyethylene terephthalate yarn. The yarn has the following physical properties:

Diameter: .005(5 mils or 0.127 mm)
Tenacity: 6.2 grams per denier (110,000 psi)

Initial Modulus = 112 grams per denier (1,980,000 psi)

I (moment of inertia): $\frac{\pi r^4}{64}$

Calculated Bending Stiffness = $E \times I$
$EI = 3.8 \times 10^{-6}$ lb. in^2.

The fusible fiber, Celbond, is composed of a polyester core and a copolyester or polyethylene sheath. It is the sheath of the fiber that provides the adhesion. The sheath resins available melt in the 110°–200° C. range, whereas the core resin melts at about 260° C. The fiber can either be spun into a yarn itself and combined with the monofilament or it can be combined directly with the monofilament using the core spinning process. This produces a yarn with a monofilament core with the Celbond fibers wrapped about it forming a sheath.

The fusible component may be a fiber composed entirely of fusible resin, where the entire fiber would melt, not just the sheath. It is also possible to use multifilament yarns, whether they are bicomponent or single component, in place of staple yarn. The low temperature melting resin may also be applied directly to the outside of the monofilament component of the filling yarns through coextrusion or post coating processes. This would replace the use of the celbond fiber in the Example.

During the heat setting process, when the tubing is being formed into a tubular vascular graft, the bicomponent celbond fiber fuses to the orthogonal warp yarns. This means that the filling and warp yarns are fused together at every interlace. This fusing allows the finished graft to be cut at any angle without the yarns shifting, separating, or ravelling.

Stretch is built into the graft by weaving the fabric with 25 to 50% fewer picks per inch than in the finished graft. During the finishing process, the tubing is compressed longitudinally 25 to 50% while on a forming mandrel, and heat set. Heat setting in this manner causes the warp yarns to crimp and buckle, which builds stretch into them. It is this stretch that allows the finished grafts to be flexible longitudinally without the need to crimp the surface of the graft.

The stiffer monofilament component of the filling yarn can be any compatible yarn, such as polyethylene terephthalate, polyurethane, polytetrafluoroethylene or silicone. It provides mechanical strength, dimensional stability and radial rigidity which maintains an open lumen for normal blood flow and provides the necessary burst strength. The multifilament warp yarns provide the necessary texture and cover for tissue adhesion and ingrowth on the outer surface and assist in controlling porosity of the graft. The velour prepared loops are of multifilament warp pile yarns on the outer surface only. In the preferred single velour construction, the external velour surface promotes tissue adhesion and ingrowth. The inner surface has a fine, low profile which promotes smooth, thin neointima formation.

The particular selection of multifilament warp yarns together with the stiffer combined fusible staple yarn and monofilament filling yarns provide a graft having improved kink resistance over a wide range of diameters. Thus, smaller bending radii can be achieved without occluding.

FIG. 1 illustrates the weaving pattern of a woven vascular graft substrate 11 prepared in accordance with a preferred embodiment of the invention. Substrate 11 is woven from a plurality of warp ends 12 and filling yarn 13. FIG. 2 is a schematic of substrate 11 in cross-section with a smooth interior surface 14 and a velour exterior surface 16 having loops 17 of multifilament warp yarns 19 which stand away from the surface of the graft.

Referring to FIG. 1, warp ends 12 include ground warp ends of multifilament yarn 18. In the illustrated embodiment multifilament yarn 18 is a one ply fifty denier untexturized unshrunk (flat) polyethylene terephthalate (Teijin) yarn (1/50/48) (single ply/50 denier/48 filaments) with a 5z twist. The loop or pile component 19 of warp yarns 12 is a multifilament yarn which alternates with each end of ground warp ends 18. In substrate 11, multifilament warp yarn 19 is a texturized 2/50/48 (2 ply/50 denier/48 filamament) with 1.5s twist polyethylene terephthalate (Teijin) yarn.

Filling yarn 13 is a combination of a monofilament yarn component 21 combined with a fusible staple yarn component 22 as shown in detail in the cross-section of FIG. 3. Fusible yarn 22 which is formed from bicomponent staple fibers 25 having a polyester core 23 with a low melting temperature sheath of a copolyester resin 24 surrounding core 23 as shown in the enlarged cross-sectional view of a single fiber 25 in FIG. 4. Fusible yarn 22 is 40 cc (English Cotton Count) Celbond Type K54, formed from 2 denier/2" staple fibers with a twist multiplier of 4 (about 25 turns per inch) having a sheath melting point of 110° C. The components are plied together with or without twisting prior to weaving.

FIG. 5 is a perspective view of a tubular graft 31 prepared in accordance with the invention. Graft 31 has a smooth inner surface 32 and external raised fabric velour surface 33 having a multiplicity of outwardly extending loops 34. Similarly, FIG. 6 illustrates a bifurcated graft 41 having a main body segment 42 and two legs 43 and 44. Legs 43 and

44 are joined to main body 42 at a crotch 46 which is generally reinforced by a row of stitches 47 to maintain as tight an initial porosity of the graft as possible. Graft 41 has a smooth interior surface 48 and an external surface 49 having loops 51. As is evident from the weaving pattern of FIG. 1, loops 34 and 51 of grafts 31 and 41, respectively are formed from multifilament warp yarns. In substrate 11 warp yarns 19 are texturized unshrunk polyester yarns.

After weaving substrate 11 in the pattern as shown in FIG. 1, tubular grafts 31 and 41 are cut, then scoured and washed in a hot bath which results in about 10 to 30 percent shrinkage or relaxation. The tubes are then subjected to a first heat setting step by placing on a specific straight size mandrel in a longitudinally stretched condition and placed in a convection oven at 175° C. for about 20 minutes to give the graft a rounded condition and fuse the Celbond yarns to the yarns in contact with it. The grafts are then subjected to a second heat setting step on the same size mandrel, but compressed longitudinally about 25 to 50 percent. This second heat setting step in the compressed state builds in longitudinal stretch and structural integrity and kink resistance without the need to crimp the graft wall. The grafts can also be heat set in a non-straight condition to create shaped grafts, such as an aortic arch, which will not have to be bent or shaped by the surgeon during implantation.

As shown in FIGS. 5 and 6, tubular woven vascular grafts and 41 prepared in accordance with the invention are not crimped in order to maintain an open lumen. This is due to inclusion of the relatively stiffer monofilament component 21 in filling yarns 13 and fusing of bicomponent yarn 25 to orthogonal warp yarns 12.

The specifications of the yarns utilized and substrate 11 are set forth in the following Example. This Example is presented for purposes of illustration and is not intended in a limiting sense.

EXAMPLE

Seven sizes of tubular grafts were woven with the following yarns in the pattern of FIG. 1.

TUBULAR WEAVE CONSTRUCTION:

Ground weave for lattice structure-plain:
Flat weave for loop or pile surface:
Warp crowfoot (floats on outside surfaces, See FIG. 2)
alternates on every other end (See FIG. 1)
YARN CONSTRUCTION:

Warp Ground - 1/50/48 (5z) Teijin Polyester.
Warp Pile - 2/50/48 (1.5s) Texturized Unshrunk Polyester Teijin.
Filling - 5 mil PET Monofilament wound together with
40 cc Celbond K-54 polyester.
Density Description

SLEY: 320 ends per inch (40 dents per inch × 8
ends per dent)
PICKS: 44 picks per inch layer (88 total in tubular form)
inserted, 46 relaxed (off loom)
TUBE DESCRIPTION

GREIGE INSIDE DIAMETERS: 4.3, 5.3, 6.3, 7.3, 8.3,
9.3 & 10.3 mm
FINISHED INSIDE DIAMETER: 4, 5, 6, 7, 8, 9 & 10 mm

The velour was formed by weaving every other warp end in a crowfoot pattern, which allows the warp yarn which formed the loop to float over three picks and under one pick. The remaining adjacent ends form a plain weave.

After weaving, the single velour graft materials of Example 1 were cut, scoured at 80° C. in water and detergent bath, and thoroughly rinsed, dried, and then rinsed in a hot water bath at about 70° C. to remove trace chemicals and dried. The graft tubes shrank about 10–20 percent in length.

The tubes were then placed on an appropriately sized straight mandrels in a longitudinally stretched condition and heat set at 175° C. for 20 minutes in a convection oven to give a round shape and fuse the Celbond yarns. The tubes were then compressed longitudinally about 30 to 40 percent of their length and heat set again on the same size mandrel at 175° C. for 20 minutes in a convection oven. Preferably, the compression is about 25–50% in length.

The porosity of the grafts were estimated to be about 1000 ml/min/cm^2.

The longitudinal compliance of a tubular vascular graft is a relative measurement of the ability of the graft to elongate at a given force and is expressed as the percent elongation per kilogram force. The grafts prepared in the Example were stretched about 30% in length from 0 to 1 when tension was increased Kg. This allows the graft to bend easily without kinking. The fusible component did not adversely affect the feel or flexibility compared to conventional woven grafts.

After fusing in the heat setting steps, the yarns could not be unravelled from the tubing ends, even after cutting the graft ends at angles.

The characteristics and properties of the grafts woven in accordance with the invention can be varied as desired by selection and combination of the starting warp and filling yarns and the weaving pattern. In the illustrated examples, the warp ground yarns are multifilament untexturized unshrunk (or flat) polyester yarn, but could be preshrunk or unshrunk in untexturized form or a combination of yarns alternating in desired patterns. The preferred warp yarn forming the pile is a multifilament texturized polyester, but could also be preshrunk or unshrunk in texturized or untexturized form. The sole limiting feature is that there be sufficient multifilament yarns considering the desired end results. The filling yarn is a composite fusible bicomponent yarn combined with a monofilament polyethylene terephthalate yarn.

It will thus be seen that the objects set forth above among those made apparent from the preceding description, are efficiently attained and, since certain changes may be made in the above article without departing from the spirit and scope of the invention, it is intended that all matter contained in the above description and shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

It is also to be understood that the following claims are intended to cover all of the generic and specific features of the invention herein described and all statements of the scope of the invention which, as a matter of language, might be said to fall therebetween.

What is claimed is:

1. A ravel-resistant and self-supporting tubular synthetic fabric vascular graft resistant to kinking, comprising:

a plurality of warp yarns woven with at least one filling yarn to form a weave;

the filling yarn including a stiffening component in the weave which is heat set in a rounded condition to render the tubular graft self supporting; and

the weave including a low melting temperature fusible component having a melting temperature lower than the other yarns to bond to adjacent yarns when heat set.

2. The woven vascular graft of claim 1, further including a low melting temperature fusible component in the filling yarn.

3. The woven vascular graft of claim 1, wherein the low melting fusible component is a bicomponent fiber having a high melting temperature core and a low melting temperature polymer sheath.

4. The woven vascular graft of claim 1, wherein the warp yarns include multifilament textile yarns.

5. The woven vascular graft of claim 4, wherein the multifilament yarns are polyethylene terephthalate.

6. The woven vascular graft of claim 5, wherein the multifilament polyethylene terephthalate warp yarns are unshrunk untexturized yarns.

7. The woven vascular graft of claim 1, wherein the stiffening component is a monofilament yarn of polyethylene terephthalate.

8. The woven vascular graft of claim 1, wherein the monofilament yarn is a 5 mil yarn.

9. The woven vascular graft of claim 8, wherein the vascular graft is a tube with a single outside velour surface and a smooth interior surface, the velour surface formed from warp pile yarns of texturized multifilament yarn.

10. The woven vascular graft of claim 1, wherein the graft has at least one velour surface of a plurality of warp pile yarns of multifilament yarns.

11. The woven vascular graft of claim 10, wherein the warp pile yarns alternate between each said warp yarn.

12. The woven vascular graft of claim 10, wherein the multifilament warp pile yarns are polyethylene terephthalate.

13. The woven vascular graft of claim 12, wherein the warp pile yarn is texturized polyethylene terephthalate.

14. The woven vascular graft of claim 10, wherein the vascular graft is a tube with a single outside velour surface and a smooth interior surface, the velour surface formed from warp pile yarns of preshrunk texturized multifilament yarn.

15. The woven vascular graft of claim 1, wherein the graft has been heat set to bond the fusible components to adjacent yarns.

16. The woven vascular graft of claim 1, wherein said weave is set in a longitudinally-compressed state to provide said graft with longitudinal compliance and kink resistance.

17. The woven vascular graft of claim 1, wherein said stiffening component is present in each pick of the weave.

18. The woven vascular graft of claim 1, wherein said weave further comprises a plurality of pile yarns for providing a velour surface on at least one side of said weave.

19. A self-supporting singular velour woven synthetic fabric vascular graft, comprising:

a plurality of warp ground yarns and a plurality of warp pile yarns woven together with at least one filling yarn to form a weave;

the filling yarn including a stiffening component in the weave which is heat set in a rounded condition to render the graft self-supporting; and

the weave including a low melting temperature fusible component which melts at a lower temperature than the other yarn to bond to adjacent yarn when heat set.

20. The woven vascular graft of claim 19, wherein the filling yarn includes a yarn of low melting fusible fibers wound together with the stiffening component.

21. The woven vascular graft of claim 19, wherein the low melting temperature fusible component is a yarn of bicomponent fibers having a core surrounded by a low melting temperature polymer sheath wound together with a monofilament yarn.

22. The woven vascular graft of claim 19, wherein the warp pile yarns alternate with the warp ground yarns.

23. The woven vascular graft of claim 22, wherein the vascular graft is a tube with a single outside velour surface and a smooth interior surface, the velour surface formed from warp pile yarn of texturized multifilament yarn.

24. The woven vascular graft of claim 22, wherein the warp ground yarn includes unshrunk untexturized yarn.

25. The woven vascular graft of claim 19, wherein the graft has been heated sufficiently to bond the fusible component to adjacent yarns.

26. The self-supporting single velour woven synthetic vascular graft of claim 19, wherein said weave is set in a longitudinally-compressed state to provide said graft with longitudinal compliance and kink resistance.

27. The self-supporting single velour woven synthetic vascular graft of claim 19, wherein said stiffening component is present in each pick of the weave.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,509,931
DATED : April 23, 1996
INVENTOR(S) : Schmitt

It is certified that error appears in the above-indentified patent and that said Letters Patent is hereby corrected as shown below:

At. Col. 2, line 62,	"grafts described above," should be --grafts described above.--;
At Col. 2, line 67,	"an open lumen," should be --an open lumen.--;
At Col. 4, line 24,	"an enhanced filling" should be --an enlarged filling--;
At Col. 5, line 12,	"The diameter m" should be --The diameter--;
At Col. 5, line 63,	"the celbond" should be --the Celbond--;
At Col. 5, lines 66-67,	"the bicomponent celbond" should be --the bicomponent Celbond--;
At Col. 7, lines 26-27,	"grafts and 41" should be --grafts 31 and 41--;
At Col. 7, line 52,	"Density Description" should be -- DENSITY DESCRIPTION:--; and

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,509,931
DATED : April 23, 1996
INVENTOR(S) : Schmitt

It is certified that error appears in the above-indentified patent and that said Letters Patent is hereby corrected as shown below:

At Col. 7, line 54, "per inch layer" should be --per inch per layer--.

Signed and Sealed this
Sixth Day of August, 1996

Attest:

BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks

Nov. 25, 1969 I. B. MEDELL 3,479,670

TUBULAR PROSTHETIC IMPLANT HAVING HELICAL THERMOPLASTIC WRAPPING THEREAROUND

Filed Oct. 19, 1966

Fig. 1.

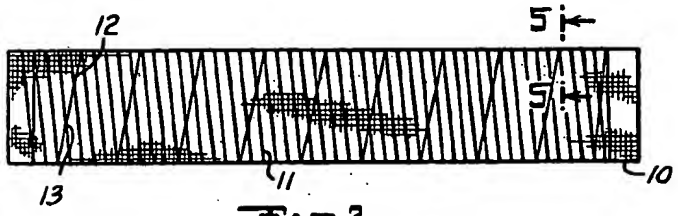


Fig. 2.

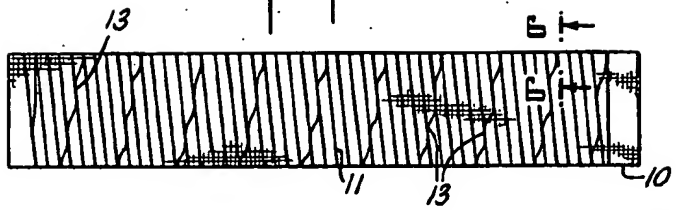


Fig. 3.

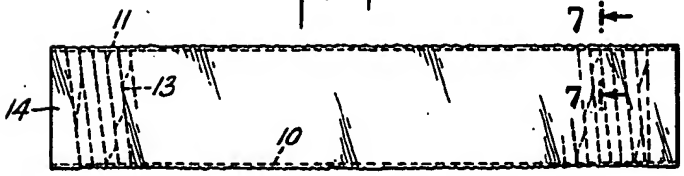


Fig. 4.

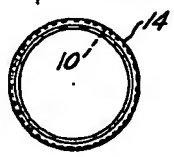


Fig. 5.

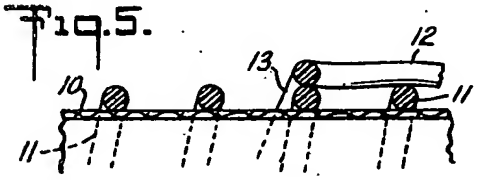


Fig. 7.

Fig. 6.

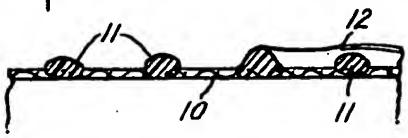
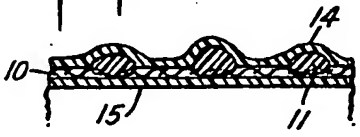


Fig. 8.



INVENTOR.
IRVING BRIDGMAN MEDELL
BY Robert W. Kell
ATTORNEY

United States Patent Office 3,479,670 Patented Nov. 25, 1969

3,479,670

TUBULAR PROSTHETIC IMPLANT HAVING HELICAL THERMOPLASTIC WRAPPING THEREAROUND

Irving Bridgman Medell, Monmouth Junction, N.J., assignor to Ethicon, Inc., a corporation of New Jersey

Filed Oct. 19, 1966, Ser. No. 588,670
Int. Cl. A61f 1/00; A61b 17/04; F16l 11/00
U.S. Cl. 3—1 4 Claims

ABSTRACT OF THE DISCLOSURE

An open-mesh non-absorbent cylindrical tube is wrapped with two sections of polypropylene monofilament to form a right-hand helix and a left-hand helix along the surface of the tube. This composite structure is heated to the fusion temperature of polypropylene causing the polypropylene monofilaments to fuse into and partially penetrate the exterior surface of the tube and causing the monofilaments to fuse together at the points of intersection. The tubes so obtained are resistant to collapse and kinking and may be coated with a dispersion of collagen fibrils to reduce permeability. The product so obtained has utility as an esophageal graft.

The present invention relates to reinforced-fabric, tubular prostheses adapted to be placed permanently in the human body and to a method of making the same. More particularly, this invention relates to tubular prostheses that are reinforced with a fused monofilament having utility in the surgical repair of body ducts, such as, the ureter, the bile duct, the esophagus, and the blood vessels.

Problems have occurred in the use of tubular prostheses to repair vessels and ducts of small diameter, most particularly if there is insufficient pressure within the vessel to maintain an open lumen. A primary problem of esophageal reconstruction is stricture at the anastomosis line after healing. Attempts have been made to avoid the collapse or kinking of such fabric tubes by crimping. While a crimped tube is more flexible than an uncrimped tube and will resist kinking and collapse, these advantages are reduced or eliminated during the healing process as the ingrowth of tissue immobilized the crimp and decreases the flexibility of the prostheses. Moreover, the irregularities of the internal surfaces of the tube produce turbulence and increased resistance to fluid flow.

The present invention has for its principal object the provision of flexible tubes constructed of fabric and reinforced with a polypropylene monofilament that has been fused to united the monofilament and the fabric.

A further object of the invention is the provision of fabric tubes that are not subject to kinking or collapsing in any desired diameter or length suitable for use with human body ducts, arteries, or veins.

It has now been discovered that an improved prosthesis can be constructed using as a framework or support a synthetic fiber having a high melting point, such as Dacron, a fiber made from terephthalic acid and ethylene glycol, or Teflon, a tetrafluoroethylene polymer, both of which are manufactured by E. I. du Pont de Nemours and Company. Dacron or Teflon may be knitted or woven to form a tube having a wide mesh thus permitting easy invasion by the host tissue into the interstices between the non-absorbable fibers. The tube may be made more resistant to collapse and kinking by fusing to the surface of the tube a section of polypropylene monofilament. The polypropylene monofilament is wrapped around the tube and heated to its fusion temperature causing it to fuse into and partially penetrate

the exterior surface of the tube. Preferably, the external surface of the tube is wrapped with two sections of thermoplastic monofilament, the first section forming a right-hand helix along the surface of the tube and the second section forming a left-hand helix and intersecting the first section at frequent intervals.

The invention will appear more clearly from the following detailed description when taken in connection with the accompanying drawings, showing by way of example, a preferred embodiment of the inventive idea. Referring now to the drawings,

FIGURE 1 is a side elevational view of a reinforced, fabric tube;

FIGURE 2 is a side elevational view of the reinforced fabric tube of FIGURE 1 following heat treatment;

FIGURE 3 is a side elevational view, partly in section, of a reinforced tube coated with collagen;

FIGURE 4 is an end view of the tube illustrated in FIGURE 3;

FIGURE 5 is an enlarged sectional view taken on the line 5—5 of FIGURE 1;

FIGURE 6 is an enlarged sectional view taken on the line 6—6 of FIGURE 2;

FIGURE 7 is an enlarged sectional view taken on the line 7–7 of FIGURE 3; and

FIGURE 8 is an enlarged sectional view of a reinforced fabric tube that has been coated with collagen.

The non-absorbable fabric, either Dacron or Teflon, may be knitted, crocheted, woven, or braided in the shape of a tube, Y-tube, etc. Optionally, a fabric tulle of Dacron or Teflon may be rolled or cut and sewed with suitable thread to form the desired shape. The tube is then wrapped with a low melting, thermoplastic monofilament as shown in the drawings.

Referring now to FIGURE 1, there is shown a knitted fabric tube of Dacron generally indicated at 10 around which is wrapped a first helix of polypropylene monofilament 11. A second section of polypropylene 12 is wrapped around the fabric tube on top of the monofilament 11 to form a second helix, the pitch of which is greater than and opposite to that of the first helix.

After the helical winding of polypropylene has been applied to the fabric tube, the entire assembly is heated in an oven to about 208° C. and maintained at this temperature for about 1 hour. Under these conditions, the polypropylene strands 11 and 12 fuse together at their points of intersection 13, as best indicated in FIGURE 2. The fused polypropylene also penetrates to some extent into the interstices of the fabric 10. When cooled to room temperature, the fabric tube is surrounded by a rigid, integral grid of polypropylene that is united with and supports the fabric tube.

The effect of heating the polypropylene monofilament is best illustrated in FIGURES 5 and 6, which show the appearance of a tube wrapped with polypropylene before and after the heat treatment. The extent to which the filament has fused and has penetrated the fabric of the tube is particularly evident in FIGURE 6.

FIGURE 7 illustrates a section of a reinforced, fabric tube that has been coated on the exterior surface with a layer 14 of collagen or gelatin to render the fabric prosthesis blood tight. Its use as an esophageal graft requires the protein layer to render it impermeable to bacteria, fluids, etc.

FIGURE 8 is a similar view of a prosthesis that has been dipped to apply a coating 14 to the exterior surface of a fabric tube and a coating 15 to the interior surface thereof.

The present invention is more fully described and explained in the following examples. It is to be understood,

however, that our invention is not to be limited to any specific form of materials or conditions set forth in the examples, but is limited solely by the description in this specification and the appended claims. Throughout the specification and the examples which follow, all quantities are expressed in parts by weight.

EXAMPLE I

A venous graft is constructed of knitted Dacron with an internal diameter of 5 millimeters. This tube is placed on a Teflon-covered mandrel and is wrapped with a double helix of size 2–0, clear, monofilament polypropylene. The pitch of the helix is not critical but preferably will approximate the diameter of the tube. The Dacron tube with its clear, monofilament, polypropylene, helical overwrap is heated at 208° C. for 1 hour. After cooling at room temperature for ½ hour, the graft is removed from the mandrel.

EXAMPLE II

An esophageal graft is prepared from a knitted Dacron tube. The Dacron tube is placed on a Teflon-covered mandrel and wound with a double helix of 2–0, clear, monofilament polypropylene; the pitch of the helices approximating the diameter of the tube. The Dacron tube is then heated at 208° C. for 1 hour to fuse the polypropylene overwrap. The tube is then cooled to room temperature, and the mandrel is removed.

The reinforced Dacron tube is next immersed in an acidic, aqueous disperson of collagen fibrils prepared as described in Example I of U.S. Patent No. 3,272,204, and a vacuum is applied to the vessel containing the tube and collagen disperson to remove air bubbles trapped in the interstices of the fabric.

The coated fabric tube is removed from the collagen dispersion, and the collagen fibrils are neutralized with a dilute solution of ammonium hydroxide and air dried at room temperature for 24–48 hours. The dried collagen coating is tanned by immersing the coated fabric tube in an aqueous solution containing 0.05 percent by weight formaldehyde for two and one-half hours. The tube is then removed from the tanning bath and dried at room temperature for 24 to 48 hours.

EXAMPLE III

A tubular, arterial graft is constructed of knitted Teflon. The porosity of the knitted fabric is such that 10,000 mls. of water per minute will pass through 1 square centimeter of the fabric under a pressure of 120 millimeters of mercury. The Teflon tube is placed on a mandrel and wound with a double helix of 2–0, polypropylene monofilament. The Teflon tube is then heated at 208° C. to fuse the polyethylene overwrap. The tube is cooled to room temperature, and the mandrel is removed.

The exterior surface of the reinforced Teflon tube is next coated with an acidic aqueous dispersion of collagen fibrils prepared as described in Example I of U.S. Patent No. 3,272,204; and the collagen coating is neutralized, tanned, and dried as described above.

EXAMPLE IV

An esophageal graft is prepared as described in Example II above by substituting Teflon for Dacron in constructing the knitted tube.

While the invention has been described in detail according to the preferred method of carrying out the process and yielding the products, it will be obvious to those skilled in the art, after understanding the invention, that changes and modifications may be made (without departing from the spirit or scope of the invention), and it is intended in the appended claims to cover such changes and modifications.

What is claimed is:

1. A surgical prosthesis comprising:
   an open mesh, non-absorbable, cylindrical tube manufactured of a non-absorbable material selected from the group consisting of tetrafluoroethylene polymer and polyethylene terephthalate; and
   a helical wrapping of polypropylene monofilament around the external wall of the tube, said thermoplastic monofilament being fused and united to the external surface of the tube.

2. The surgical prosthesis of claim 1, wherein the interstices of the fabric are filled with a body-absorbable substance consisting of collagen fibrils, whereby the prosthesis is rendered blood tight.

3. The surgical prosthesis of claim 1, wherein the non-absorbable material is polyethylene terephthalate.

4. The surgical prosthesis of claim 1, wherein the non-absorable material is tetrafluoroethylene polymer.

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DALTON L. TRULUCK, Primary Examiner

U.S. Cl. X.R.

128—334; 138—125, 129; 156—306, 425

US005990378A

United States Patent [19]

Ellis

[11] Patent Number: 5,990,378

[45] Date of Patent: *Nov. 23, 1999

[54] TEXTILE SURGICAL IMPLANTS

[75] Inventor: Julian Garth Ellis, Nottingham, United Kingdom

[73] Assignee: Bridport Gundry (UK) Limited, Somerset, United Kingdom

[*] Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

[21] Appl. No.: 08/652,316

[22] Filed: May 23, 1996

[30] Foreign Application Priority Data

May 25, 1995 [GB] United Kingdom 9510624

[51] Int. Cl.[6] A61F 2/02

[52] U.S. Cl. 623/11; 623/1; 623/12; 623/13; 606/151; 606/154

[58] Field of Search 606/151, 153–155, 606/213–216, 228–230; 623/1, 11–15, 901, 66

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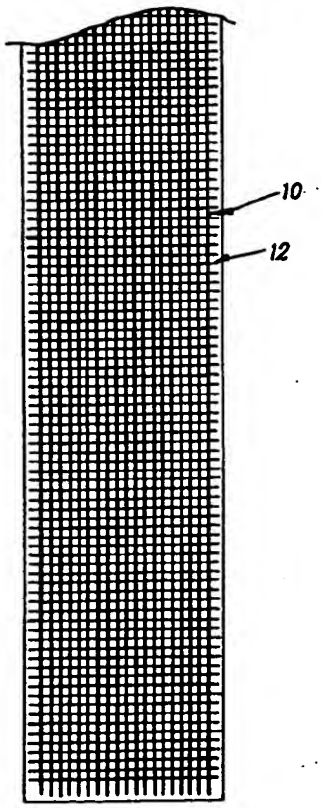
Primary Examiner—Michael J. Milano
Assistant Examiner—Tram A. Nguyen
Attorney, Agent, or Firm—Salter & Michaelson

[57] ABSTRACT

A textile surgical implant includes a base cloth, and an array of fibers provided on the base cloth. The base cloth is removable from the fibers before or after the location of the implant in a patient. A method of making a textile surgical implant is further disclosed. The method includes the step of placing an array of fibers on a base cloth by embroidery. The base cloth is removable from the fibers before or after the implant is implanted.

25 Claims, 3 Drawing Sheets



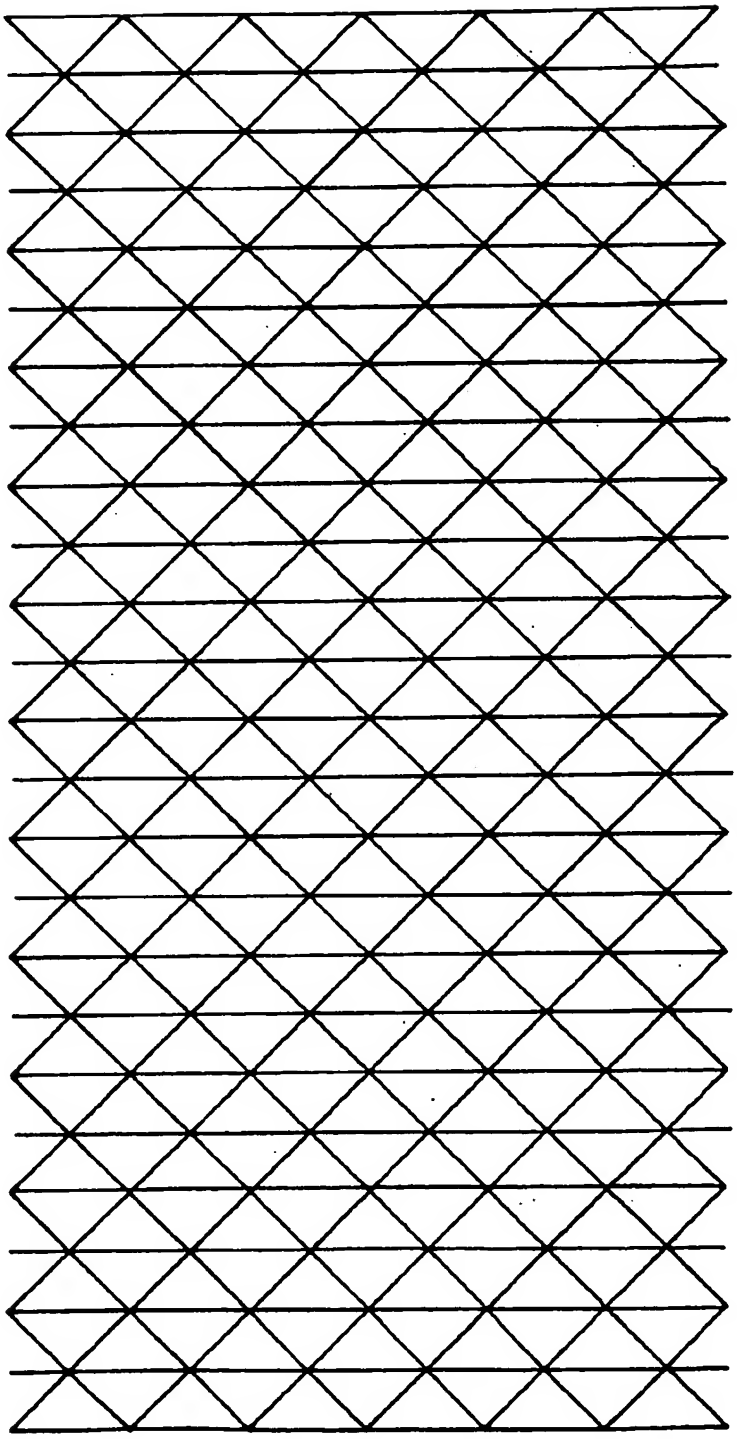


FIG. 1

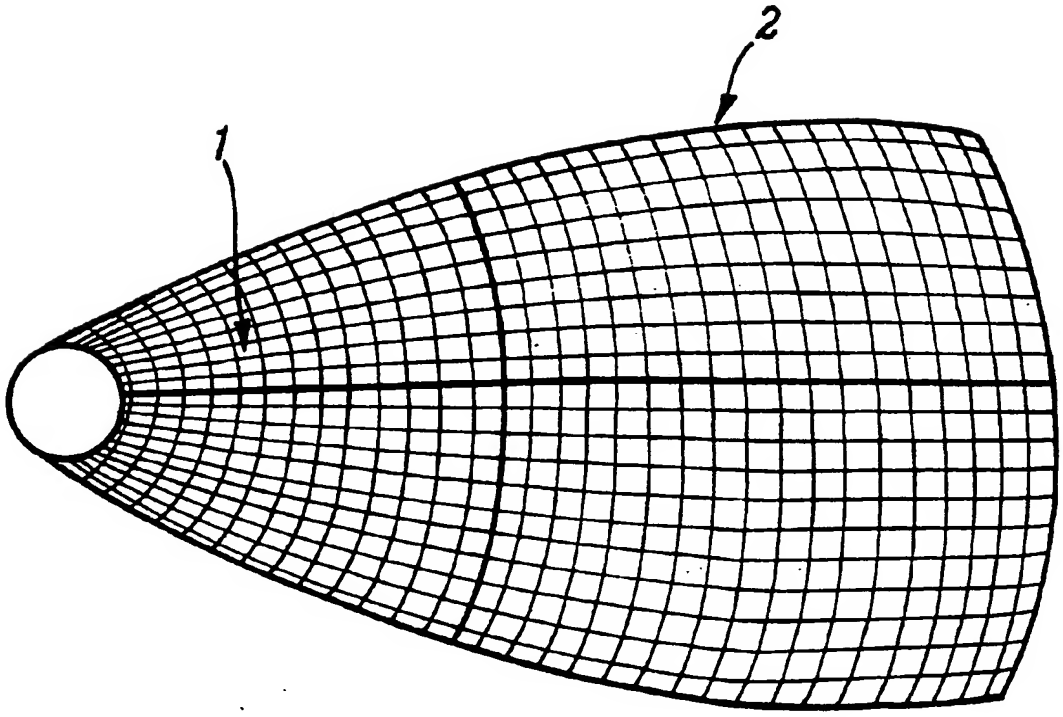


FIG. 2

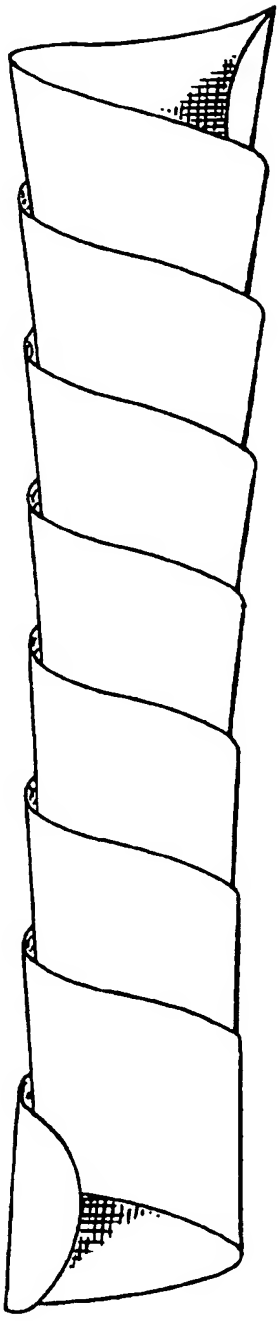


FIG. 3

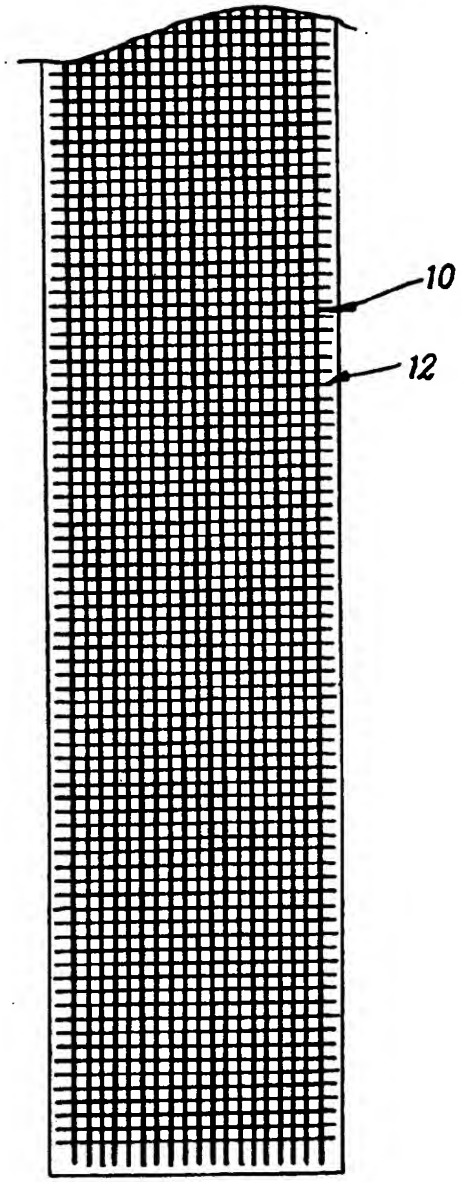


FIG. 4

TEXTILE SURGICAL IMPLANTS

BACKGROUND OF THE INVENTION

This invention relates to a textile surgical implant.

The manufacture of textile surgical implants often requires the manufacture of a low number of items. Modern textile manufacturing methods, however, are usually only cost effective if large numbers are produced. An advantage of high volume automatic manufacturing methods is that the articles manufactured are almost exactly alike. Such similarity is required by the needs of modern scientific surgery, in order that all patients shall be treated alike and that there is no untoward variation from implant to implant.

It is, therefore, desirable that textile implants should be able to be made cost effectively in small numbers on machinery that is mechanically or electronically controlled in such a way that each item produced to the same design will be virtually identical.

It is also desirable that the design method used shall be simple and quick to carry out, in order to minimise design costs. Low design costs also facilitate the cost-effective production of implants made to individual measurements, which may be desirable for unusual medical conditions or for use in patients where it is necessary to produce an implant of an exact size to fit that person.

Ideally a textile implant will have the textile fibres placed in a position and direction which accord with the design requirements in order that they may carry out their function correctly, whether it be load-bearing or otherwise.

The present invention is intended to deal with the above-mentioned problems.

SUMMARY OF THE INVENTION

According to the present invention there is provided a textile surgical implant comprising an array of fibres wherein the fibres forming the implant are placed in position in the implant by embroidery.

The term implant as used herein is not confined solely to implants that are intended to be surgically or otherwise implanted in the body, but also includes stents and the like such as are implanted in the oesophagus.

Embroidery is normally defined as work with a needle and thread upon cloth. In conventional embroidery the fibres are placed with a needle according to the requirements of the aesthetic design selected. In the manufacture of a textile surgical implant, the fibres can be placed according to the functional requirements of the design, for example so that one or more yarns in the structure may efficiently carry a load in an artificial ligament.

Many modern embroidery machines comprise a sewing head above an X-Y plotter. The plotter can be moved with great precision below the needle head (or vice-versa) so that the sewing head moves relative to the base cloth as required. The movements are controlled by punched card, or preferably, electronic computer control. An alternative arrangement is for the sewing head to move, whilst the base cloth remains stationary.

The definition of embroidery implies that the embroidery stitches must be made upon a base cloth. However, according to one embodiment of the present invention there is provided a base cloth that is soluble, so that after the implant is formed upon the base cloth, the cloth can be dissolved away and only the embroidered stitched structure remains. Using design rules known to those skilled in the art, embroidered structures can be made so that placed fibres of the

embroidery retain their structural integrity and hold together after the base cloth has been dissolved away. The dissolution can be by aqueous medium if a water soluble base fabric is used such as a base fabric made from polyvinyl acetate, or alginate. Alternatively a solvent such as acetone may be used for example when an acetate base fabric is utilised. Other base fabrics can be used which may be removed for example with acid, alkali, or organic solvent or with water, or by heat or other method.

In one embodiment of the invention a sheet material, such as polyglycolic acid, is used which degrades or is absorbed after implantation, leaving more permanent parts of the embroidered structure within the body. The implant or the base fabric can be impregnated with one or more growth factors, or angiogenic or neurogenic materials that my stimulate the production of blood vessels, nerves, or other types of tissue around and/or into the implant.

BRIEF DESCRIPTION OF THE DRAWINGS

Specific embodiments of the invention will now be described with reference to the accompanying drawings in which:

FIG. **1** is a plan view of a mesh structure;

FIG. **2** is a plan view of another mesh structure suitable for repair of a tendon or ligament;

FIG. **3** illustrates a tubular stent suitable for insertion into hollow viscera; and

FIG. **4** shows a material which can be used, inter alia, for the stent of FIG. **3**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring first to FIG. **1** a mesh structure comprises crossing threads which are laid substantially at right angles to each other. The interlocking may be achieved by a number of interlocking methods well known to those skilled in the art. Generally the interlocking is effected when the first laid down layer is crossed by the second laid part, when threads from the underthread and needle thread pass under and over the first laid thread and are interlocked by lockthread stitching as usually used for the embroidery. Different ways of interlock will give different load extension characteristics to the implant for different applications or different patients.

Such a mesh can be used to act as a reinforcing patch within the body. For example a patient may suffer from an incisional hernia where some of the internal tissues of the gut may protrude through the walls of the abdomen and the internal tissues are only held within the body by a thin layer of the body wall. The edges of the hernia may have weakened as a result of the hernia or from some other cause, which makes repair using conventional sutures difficult. The provision of a patch will assist the surgeon to obtain a good repair by enabling him to stitch the tissue at a site remote from the weak edges. The patch can also provide a scaffold on which a new tissue may grow. The requirements of any patch include that it shall have a high bursting strength, that it shall be easy to cut to size appropriate to the condition of the patient without fraying or unroving from the cut edges. Many woven structures have good properties with regard to bursting strength, but will fray readily from a cut edge. The use of a hot knife to cut thermoplastic fibres to prevent them from fraying is undesirable because of the inconvenience of carrying out this is operating theatre conditions and the sharp edges (and possibly toxic degradation products) that thermal cutting often leaves.

The provision of a thermoplastic monofilament patch where intersecting fibres in a mesh are thermally bonded is known, but any cut edges of the monofilament comprising the patch may be undesirably sharp and thermal bonding restricts the choice of fibres to those which are thermoplastic. The use of adhesives to bond the intersections of the mesh is inconvenient and may introduce a biologically incompatible component to the implant. According to the present invention any implantable fibre may be used, since the intersections of the mesh are stitched and are resistant to fraying when the mesh is out.

The invention provides a patch for the repair of tendon or ligament. For example the rotator cuff of the shoulder is difficult to repair without the use of textile reinforcement. Frequently a multiplicity of suture threads is used, but sometimes this method of reinforcement is insufficent and a reinforcing textile fabric is required. The use of a hood as described in PCT International Patent Appln. No. WO 91/03993 is one example. This provides a woven or knitted flexible fabric. The openness of the mesh is chosen so as to allow tissue ingrowth without being so open that the structural integrity is lost. The present invention includes the provision of an embroidered mesh, with areas of extra strength to carry localised heavier loads. One embodiment of this aspect of the invention is shown in FIG. 2. The mesh is ideally provided so that the holes are spaced approximately 2 mm apart and are approximately 1 mm square. The strength of the mesh is such that it must carry a minimum load of approximately body weight. The use of embroidery to form the mesh 1, has the advantage that the mesh can be locally reinforced using a different type of thread or higher concentration or density of treads or using a multiplicity of the same thread as illustrated by the bold lines referenced 2. In a preferred embodiment the main mesh 1 is made using a braided polyester fibre 0.35 mm in diameter and the reinforcement 2 is a polyester braid of 1.5 mm diameter.

The invention also provides an implant to form a sheet material having a different stiffness in one axis to the stiffness in the other axis. An implant of this kind, known as a stent, an example of which is disclosed in UK Patent Appln. No. CB 2270264 is in the form of a tube that can be compressed for insertion into the human or animal body to relieve blocking of the oesophagus or other hollow viscera by tumours or other disorders. If the coiled stent is made from stiff anisotropic sheet material and would up tightly to reduce its diameter in order to insert it within the oesophagus, the tube becomes so rigid that the stent becomes difficult to insert in some patients, for example elderly patients with stiff necks or protuberant teeth. FIG. 3 shows a self expanding solid walled tube similar to a coil spring tube. The tube can be would tightly to form a low diameter tube, or stent, which may be inserted into hollow viscera within the body and then allowed to expand, pushing aside any blockage of the hollow viscus that may have been caused by a tumour or other disorder. One example of an application is to patients in whom the oesophagus may have become blocked by a malignant tumour, making swallowing difficult.

In the embodiment of FIG. 3 the material forming the stent is made by laying stiff fibres in one axis direction of the stent onto a base embroidery material and the other direction with less stiff or no fibres. This results in an isotropic material that when wound tightly about an axis parallel to the said other direction into a low diameter tube for insertion within the hollow viscus is much less stiff in the length axis, yet retains its springiness in the radial direction. In the embodiment shown in FIG. 3 the stent is formed by winding a strip of fabric about an axis such that each turn other than the first slightly overlaps the preceding turn, thus forming a tube with a substantially continuous wall surface. In use the stent diameter is reduced by tightening the turns and then positioned in its desired location, for example in a hollow viscus, the lower stiffness of the stent in the axial direction making it easy to insert in position. Once in position the stent is allowed to expand within the hollow viscus, pushing aside a tumour or other obstruction, yet it retains flexibility in the length direction.

In a particularly preferred embodiment, the fibres are arranged as shown in FIG. 4, the longitudinal fibres 10 are monofilament polyester of high stiffness and the lateral fibres 12 are of lower stiffness monofilament polyester. If this material is coiled into a stent of the kind shown in FIG. 3 and heat-set into shape, the stent, when tightly coiled for insertion into the oesophagus of the patient, remains flexible in the longitudinal axis and may be more easily inserted.

It may be seen from the foregoing description and examples that the invention has a wide number of applications, not confined to those described herein.

What is claimed is:

1. A textile surgical implant comprising a bioabsorbable base cloth having an embroidered mesh structure disposed thereon, said base cloth being absorbed after the location of the implant in a patient.

2. An implant as claimed in claim 1, wherein the base cloth is soluble.

3. An implant as claimed in claim 1, wherein the base cloth is made from materials which will degrade after the implant is implanted in a patient.

4. An implant as claimed in claim 1, wherein the embroidered mesh structure is reinforced in at least a part thereof.

5. An implant as claimed in claim 1, wherein said implant is of substantially triangular shape.

6. An implant as claimed in claim 1, said embroidered mesh structure having fibres arranged to give greater stiffness in one direction than in another direction.

7. An implant as claimed in claim 6, comprising first fibres of a greater stiffness extending in one direction, and second fibres of a lesser stiffness extending in a second direction, the first and second directions of the fibres being substantially at right angles to one another.

8. An implant as claimed in claim 7, wherein the tube is heat set to retain its shape.

9. An implant as claimed in claim 6 formed as a tube having a radial stiffness greater than the stiffness in the axial direction.

10. An implant as claimed in claim 9, wherein the tube is formed from a strip having fibres arranged in two directions, the strip being wound about an axis.

11. An implant as claimed in claim 10, wherein the strip is wound in a plurality of turns and each turn of the strip, other than the first, overlaps the preceding turn.

12. An implant as claimed in claim 1 and comprising one or more growth factors, angiogenic and neurogenic materials.

13. A method of making a textile surgical implant comprising the step of:

embroidering a mesh structure on a bioabsorbable base cloth, said base cloth being absorbed after the implant is implanted in a patient.

14. A method as claimed in claim 13, wherein the base cloth is soluble and is removed by dissolving the base cloth in a solvent.

15. A method as claimed in claim 13, wherein the base cloth is removed by degradation after the implant has been implanted in a patient.

16. A method as claimed in claim 13 and comprising reinforcing the mesh structure in at least a part thereof.

17. A method as claimed in claim 16, wherein said mesh structure includes fibres arranged to give greater stiffness in one direction of the mesh structure than in another direction thereof.

18. A method as claimed in claim 17, wherein fibres giving grater stiffness are placed at substantially right angles to fibres giving differential stiffness.

19. A method as claimed in claim 17, wherein the mesh structures is formed as a tube having a radial stiffness greater than the stiffness in the axial direction.

20. A method as claimed in claim 19, wherein the tube is formed from a strip having fibres arranged in two directions by winding the strip about an axis.

21. A method as claimed in claim 20, wherein the strip is wound in a plurality of turns, each turn of the strip, other than the first, overlapping the preceding turn.

22. A method as claimed in claim 19 wherein the tube is heat set to retain its shape.

23. A method of making a textile surgical implant comprising the step of:

placing an array of fibers arranged as a mesh on a bioabsorbable base cloth by embroidery, said base cloth being absorbed after the implant is implanted;

wherein said fibers are arranged in the mesh to give greater stiffness in one direction of the mesh than in another direction thereof.

24. A textile surgical implant comprising a base cloth and a mesh structure of fibers provided on said base cloth by embroidery, said base cloth being made from a biocompatible material which is absorbed after the implant is implanted.

25. A method of making a textile surgical implant comprising the step of:

placing a mesh structure of fibers on a base cloth by embroidery, said base cloth being made from a biocompatible material which is absorbed after the implant is implanted.

* * * * *

US006344056B1

(12) **United States Patent**
Dehdashtian

(10) **Patent No.: US 6,344,056 B1**
(45) **Date of Patent: Feb. 5, 2002**

(54) **VASCULAR GRAFTS FOR BRIDGING A VESSEL SIDE BRANCH**

(75) Inventor: **Mark Dehdashtian**, Costa Mesa, CA (US)

(73) Assignee: **Edwards Lifesciences Corp.**, Irvine, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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(52) **U.S. Cl.** **623/1.35**
(58) **Field of Search** 623/1.23, 1.27, 623/1.32, 1.35, 1.36, 1.15

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Primary Examiner—David H. Willse
Assistant Examiner—Suzette J. Jackson
(74) *Attorney, Agent, or Firm*—Peter Jon Gluck; Vascular Therapies; Guy L. Cumberbatch

(57) **ABSTRACT**

A vascular graft for a primary vessel adapted to bridge a side branch. The graft is especially useful for providing a support tube for a primary graft in the primary vessel on one side of the side branch. The graft includes first and second tubular sections separated by a gap. A bridging member connects the first and second tubular sections across the gap and may include a relatively rigid strut to prohibit relative axial movement of the two sections. There may be one, two or more bridging members to define one, two or more apertures through which blood can flow from within the graft through to the vessel side branch. The graft may include a flexible, desirably fabric, body supported by a wireform stent that is either self- or balloon-expandable. The graft may be deployed within the abdominal aorta on both sides of the renal arteries and have two apertures for blood to flow from the aorta to the renals. The infra-renal section provides a uniform tubular anchoring surface for a trunk portion of a bifurcated graft used to repair an abdominal aneurysm extending to the iliac arteries.

22 Claims, 4 Drawing Sheets

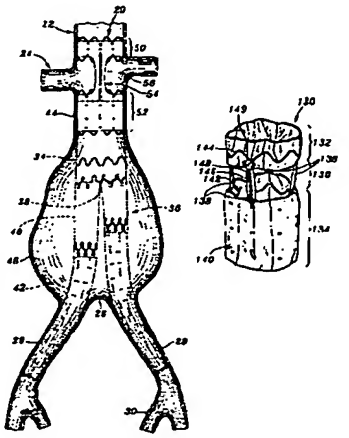

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Fig. 1

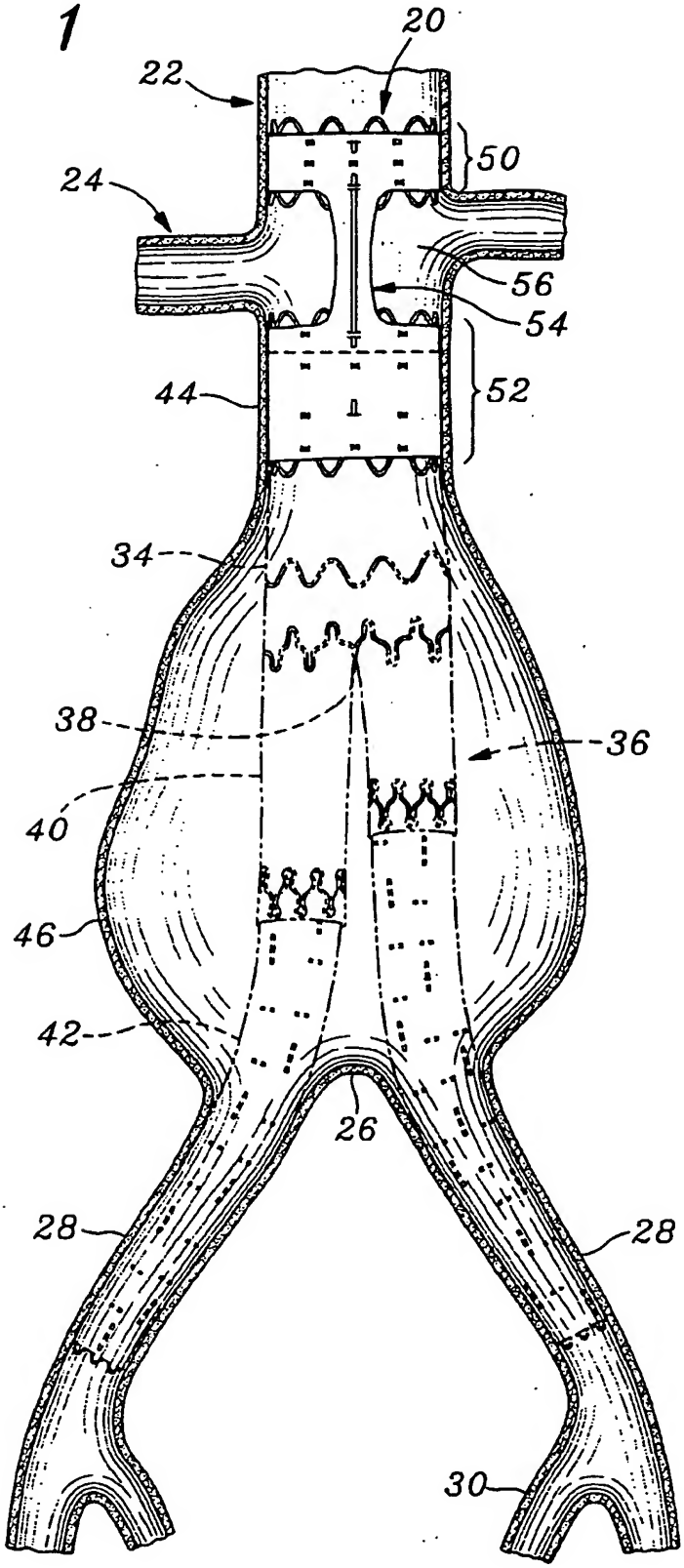


Fig. 2

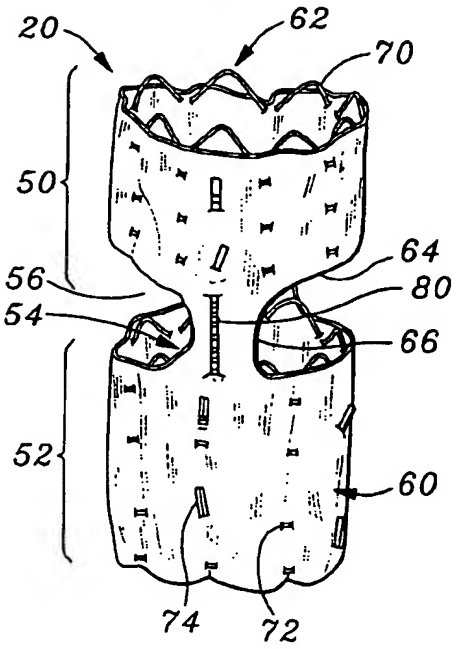


Fig. 3

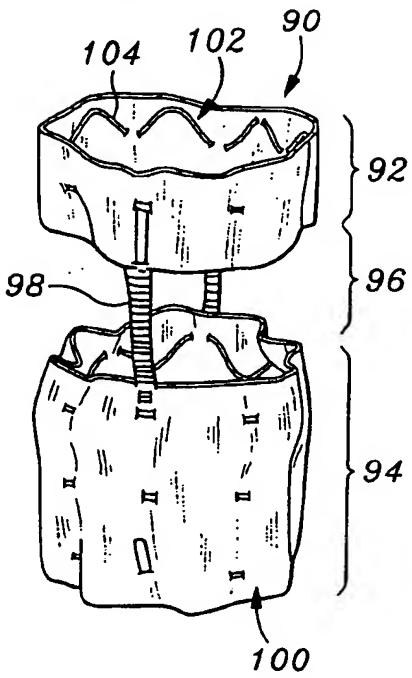


Fig. 4

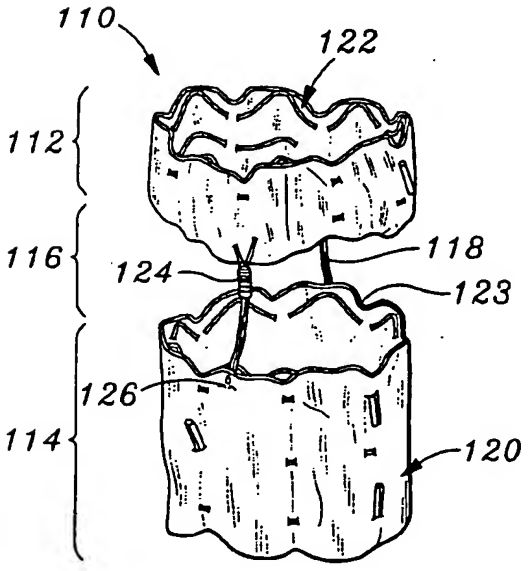
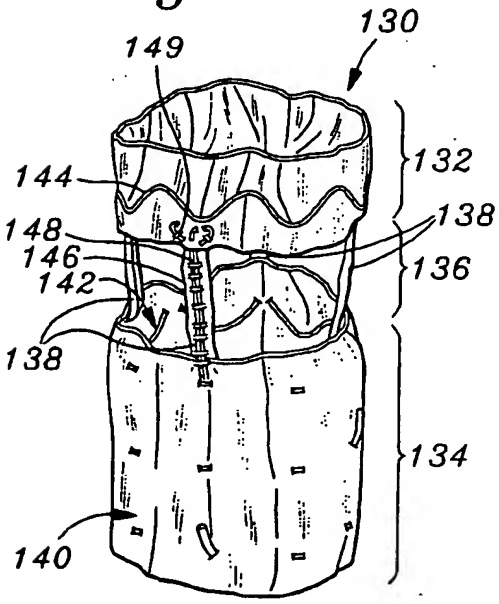


Fig. 5



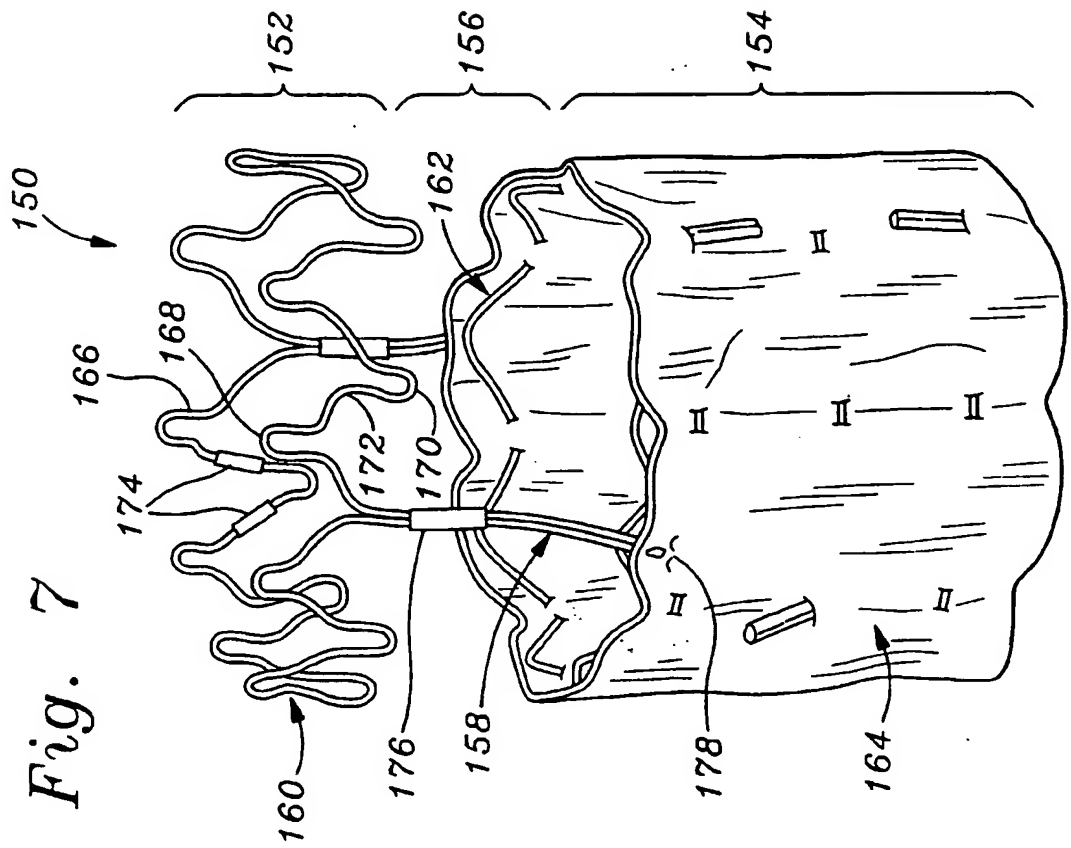

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Fig. 7

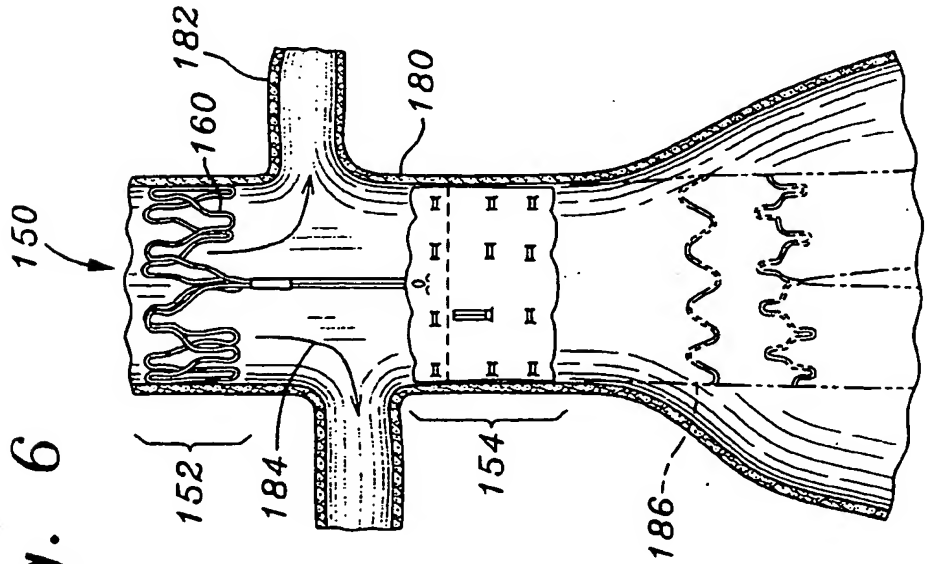
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Fig. 6

Fig. 9

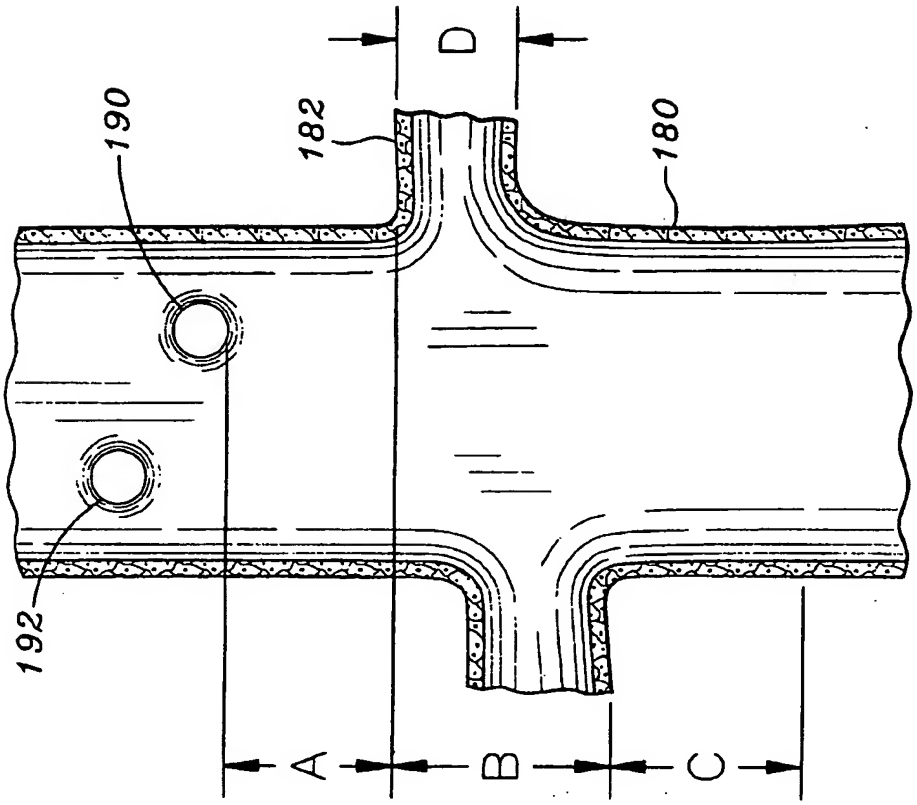
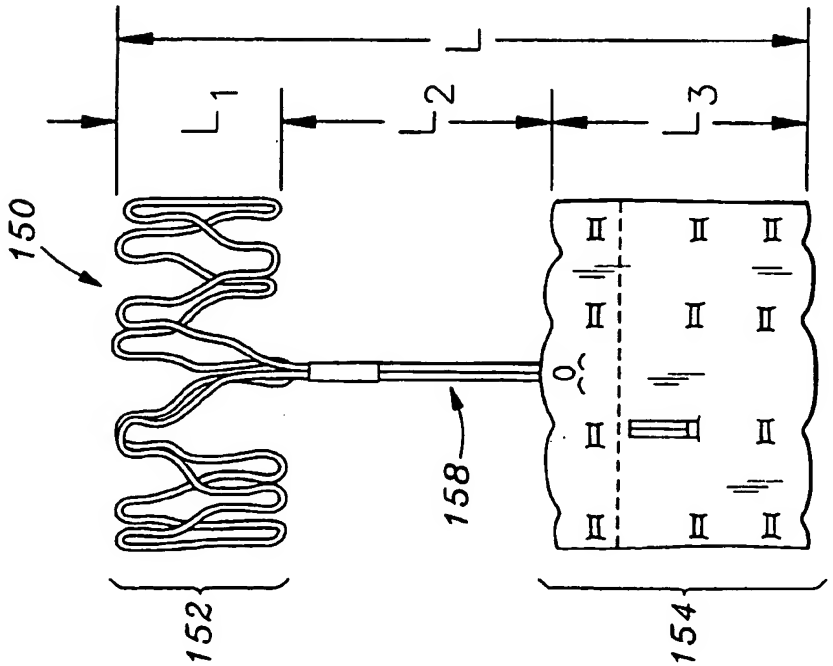


Fig. 8



VASCULAR GRAFTS FOR BRIDGING A VESSEL SIDE BRANCH

FIELD OF THE INVENTION

The present invention relates to prosthetic vascular grafts and, more particularly, to a vascular graft for a primary vessel adapted to bridge a side branch, especially for providing a support tube for a primary graft located in the primary vessel on one side of the side branch.

BACKGROUND OF THE INVENTION

An aneurysm is a ballooning of the wall of an artery resulting from weakening due to disease or other condition. Left untreated, the aneurysm may rupture, resulting in severe loss of blood and potentially death. An aneurysm in the abdominal aorta is the most common form of arterial aneurysm. The abdominal aorta connects the ascending aorta at the heart to the circulatory system of the trunk and lower body. The abdominal aorta extends downward from the heart in front of and parallel to the spine, through the thorax and abdomen, and branches off in a plurality of side vessels. Among other branching vessels, the abdominal aorta supplies the two kidneys via oppositely-directed renal arteries. Below the renal arteries, the abdominal aorta continues to about the level of the fourth lumbar vertebrae and divides at a Y-junction into the left and right iliac arteries, which supply blood to the lower extremities.

A common location for an aortic aneurysm is in the section of aorta between the renal and iliac arteries. Without rapid surgical intervention, a rupture of the abdominal aorta is commonly fatal because of the high volume of blood flow within the aorta. Conventional surgical intervention involves penetrating the abdominal wall to the location of the aneurysm to reinforce or replace the diseased section of the aorta. Typically, a prosthetic tube graft replaces the area of, or proximal and distal zones abutting, a potential rupture portion of the aorta. Unfortunately, conventional surgical intervention has resulted in substantial morbidity rates, and at the very least a protracted recovery period. Likewise, cost and other constraints militate for a longstanding need for endovascular intervention.

In recent years, methods and devices have been developed to treat an aortic aneurysm without opening up the abdominal wall. These new techniques typically involve a catheter-carried tubular graft delivered upward from the femoral artery through the iliac artery and into the region of the aneurysm. The graft normally includes a tubular graft body supported by an expandable stent, either self-expanding or balloon-expanding. The balloon-expanding type of stent naturally requires an expansion balloon, while the self-expanding type is simply deployed from the end of a tubular sheath. Implacement issues impact upon both known techniques.

If the aneurysm affects the Y-junction between the abdominal aorta and the iliac arteries, a bifurcated graft is typically used. A trunk portion of the bifurcated graft is secured to a healthy section of the abdominal aorta just below the renal arteries, and branched legs of the graft are secured within each of the iliac arteries, sometimes via a tubular extension graft. This procedure does not involve cardiopulmonary bypass, and thus blood continues to flow downward through the abdominal aorta. Certain complications arise in anchoring the graft to the inner wall of the vessel, because of the high blood flow both during the procedure and afterward. Indeed, the risk of grafts migrating within a vessel is a problem in many locations, not just in the abdominal aorta. In addition, the abdominal aorta may be aneurysmic very close to the renal arteries, which results in a fairly poor substrate within which to secure a repair graft. In fact, surgeons require various minimum lengths of healthy aortic wall below the renal arteries before an endovascular graft repair is indicated, or else a conventional invasive technique must be used. Moreover, the same consideration of a minimum healthy portion of the host vessel applies in other areas, especially with regard to the portion of the aorta adjacent the branching subclavian or carotid arteries.

A number of techniques have been proposed for anchoring grafts to vessel walls, most notably the use of barbs or hooks extending outward from graft that embed themselves into the vessel wall. Although these devices secure the graft, they may damage the vessel wall and cause complications. Alternatively, portions of the stent may extend beyond the upstream end of the graft body and be bent outward into contact with the vessel wall, either from a pre- or shape memory-bias, or from expansion of a balloon in this region.

In the context of repairing an aneurysm in the abdominal aorta, some manufacturers have provided a stent at the upper end of a bifurcated graft that extends across the renal arteries. For example, the TALENT brand of Endovascular Stent-Graft System available from World Medical of Sunrise, Florida, includes an undulating wire support frame extending above the graft body intended for supra-renal fixation. Likewise, the ZENITH AAA brand of Endovascular Graft from Cook, Inc. of Bloomington, Indiana, utilizes an undulating wire support having barbs for supra-renal fixation of the graft. However, because these wires extend across the opening of the branching renal arteries they present a certain impediment to blood flow therethrough. Moreover, any structure placed in the path of blood flow may tend to initiate the blood clotting cascade, which in turn, may generate free-floating emboli that would adversely impact the kidneys, or other organ that is perfused through the affected side branch. Because the kidneys are highly susceptible to injury from incursion of such emboli, it is highly desirable to avoid even the possibility of blood clotting at the mouth of the renal arteries.

Despite much work in this highly competitive field, there is still a need for a more secure means of anchoring a bifurcated graft in the abdominal aorta. More generally, there is a need for a more secure means of anchoring a tubular graft in a primary vessel in the vicinity of a vessel side branch.

SUMMARY OF THE INVENTION

The present invention comprises a vascular graft adapted for placement in a primary blood vessel and suited to bridge a vessel side branch. The graft comprises a tubular structure defining an outer surface, a first portion of the outer surface being sized to contact and support the blood vessel on one side of the side branch, and a second portion of the outer surface being sized to contact and support the blood vessel on the other side of the side branch. The tubular structure defines an aperture for alignment with the side branch so as to permit blood flow between the blood vessel and the side branch. The first and second portions may be separated across a gap and the graft further may include at least one bridging member traversing the gap and connecting the first and second portions so as to prevent relative axial separation of the two portions after implantation, the aperture being defined between the bridging member and the first and second portions. There are desirably at least two bridging

members and two apertures, and potentially four bridging members and four apertures. Further, the bridging member may be a relatively rigid strut.

In another aspect, the invention provides a vascular graft adapted for placement in a primary blood vessel and suited to bridge a vessel side branch, comprising:

a first tubular structure sized to contact and support the blood vessel on one side of the side branch;

a second tubular structure sized to contact and support the blood vessel on the other side of the side branch; and

at least one bridging member connecting the first and second tubular structures so as to define an aperture in the vascular graft sized for blood to flow through between the blood vessel and the side branch.

At least one of the first and second tubular structures desirably comprises a flexible graft body and a support stent, wherein the strut is directly connected to the graft body. More preferably, the flexible graft body is only provided in one of the first or second tubular structures, the other tubular structure being defined solely by the stent.

In a further aspect, the invention provides a vascular graft system adapted for placement in a primary blood vessel and adjacent a vessel side branch. The system includes a tubular support graft including a first tubular structure sized to contact and support the blood vessel on one side of the side branch, and a second tubular structure spaced from and connected to the first tubular structure and sized to contact and support the blood vessel on the other side of the side branch. The system further includes a tubular primary graft sized to co-axially couple with the first tubular structure. At least one bridging member may connect the first and second tubular structures so as to prevent relative axial separation of the two tubular structures after implantation, an aperture being defined between the bridging member and the first and second tubular structures of a sufficient size to permit blood flow though the vessel side branch. In one application of the system, the primary vessel is the abdominal aorta, the vessel side branch comprises the renal arteries, and the tubular primary graft is a portion of a bifurcated graft. In addition, at least one of the first and second tubular structures preferably comprises a flexible graft body and a support stent, and more preferably the flexible graft body is only provided in the tubular structure that is disposed infra-renally, the other tubular structure disposed supra-renally being defined solely by the stent. The stent may be self-expandable or balloon-expandable.

Methods of supporting a tubular primary graft in a primary blood vessel adjacent a vessel side branch is also provide by the present invention. One method includes,

providing a tubular support graft including a first tubular section and a second tubular section connected to the first tubular section;

delivering the tubular support graft into an implant position;

deploying the tubular support graft so that the first tubular section contacts and supports the blood vessel on one side of the side branch and the second tubular section contacts and supports the blood vessel on the other side of the side branch;

providing a tubular primary graft having a first end;

delivering the first end of the primary graft within the support graft second tubular section; and

radially expanding the first end of the primary graft against the inner surface of the second tubular section.

Another method includes the steps of:

providing a tubular primary graft having a first end;

delivering the first end of the primary graft into an implant position; and

radially expanding the first end of the primary graft against the inner surface of the blood vessel on one side of the side branch.

providing a tubular support graft including a first tubular section and a second tubular section connected to the first tubular section;

delivering the tubular support graft so that the second tubular section is within the primary graft first end; and

radially expanding the tubular support graft so that the first tubular section contacts and supports the blood vessel on one side of the side branch and the second tubular section contacts and supports the inner surface of the primary graft first end.

Either method is preferably accomplished by endoluminally delivering both the tubular support graft and the tubular primary graft.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a sectional view through an abdominal aorta showing the branching renal and iliac arteries, and illustrating one embodiment of a graft of the present invention for supporting a trunk portion of a bifurcated graft, shown in phantom;

FIG. **2** is a perspective view of the graft of FIG. **1**;

FIG. **3** is a perspective view of an alternative graft in accordance with the present invention having two planar bridging members;

FIG. **4** is a perspective view of a further graft of the present invention having two wire-like bridging members;

FIG. **5** is a perspective view of a further graft of the present invention having four bridging members;

FIG. **6** is a sectional view of the abdominal aorta in the region of the renal arteries illustrating a still further embodiment of a graft of present invention used to support the trunk portion of a bifurcated graft, shown in phantom;

FIG. **7** is a perspective view of the graft of FIG. **6**;

FIG. **8** is an elevational view of the graft of FIG. **6** showing certain axial dimensions; and

FIG. **9** is an axial sectional view of an abdominal aorta in the region of the renal arteries showing certain anatomical dimensions.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. **1** illustrates a graft **20** of the present invention deployed within a primary vessel, in this case the abdominal aorta **22**. A pair of side branches **24** is shown intersecting the primary vessel **22** at approximately the same axial location across the vessel. In the context of an abdominal aorta **22**, two important side branches are the renal arteries **24**, as shown. The abdominal aorta **22** continues downward from the renal arteries **24** and bifurcates at a Y-junction **26** into the left and right iliac arteries **28**.

The present invention provides a tubular graft within a primary vessel for supporting another tubular graft in the primary vessel in proximity to a side vessel. It should therefore be understood that although the drawings and description involve a graft in the abdominal aorta for sup-

porting another graft in the region of the renal arteries, the same principles apply whichever primary vessel or side vessel is involved. For example, as illustrated in FIG. **1**, the graft **20** could be used in the vicinity of a side branch **30** in the iliac arteries **28**. Representative conditions suitable for repair with the grafts of the present invention include the abdominal aortic aneurysm (AAA) described herein, a thoracic aortic aneurysm (TAA), and an aortic uni-iliac (AUI) aneurysm. For purpose of explanation, however, the term "side branch" will be used interchangeably herein with "renal artery," and the term "primary vessel" will be used interchangeably with "abdominal aorta."

As illustrated in FIG. **1**, the graft **20** helps anchor a trunk portion **34** of a bifurcated graft **36**, shown in phantom. The bifurcated graft **36** typically comprises the trunk portion **34** that diverges at a septum **38** into a pair of legs **40**. One or both of the legs **40** may extend a sufficient distance to form a seal within the iliac arteries **28**, or tubular extensions **42** may be provided for this purpose. The end result is that the bifurcated graft **36** (and optional tubular extensions **42**) extends from a healthy portion **44** of the abdominal aorta **22** to both of the iliac arteries **28**, spanning an aneurysmic region **46**. Once the bifurcated graft **36** is in place, blood flows therethrough and blood pressure is reduced between the aneurysm **46** and the exterior of the graft. Ultimately, the aneurysm **46** collapses inward around the graft, which remains in place.

With reference to FIGS. **1** and **2**, the graft **20** of the present invention comprises a first tubular section **50** and a second tubular section **52** connected via at least one bridging member **54**. The first tubular section **50** is spaced from the second tubular section **52** across a gap that, in conjunction with the bridging member **54**, defines an aperture **56** for blood flow. If the first and second tubular sections **50, 52** are co-linear, then the bridging member **54** is generally axially disposed. Alternatively, if the graft **20** is intended for implantation in a curvilinear vessel, the first and second tubular sections **50, 52** may be aligned along a curvilinear axis, in which case the bridging member **54** will also be generally disposed along the same curve. Still further, the graft **20** may be multi-curvate, for example S-shaped, in which case the first and second tubular sections **50, 52** and bridging member **54** will follow the multiple curves.

As illustrated in FIG. **1**, the aperture **56** is aligned with at least one of the side branches **24**. In a preferred application, the graft **20** is used to support a bifurcated graft **36** in proximity with the renal arteries **24**, and thus defines two apertures **56**, each aligned with one of the renal arteries. In this context, the first tubular section **50** is secured in contact with a supra-renal portion of the abdominal aorta **22**, while the second tubular section **52** is secured in contact with an infra-renal portion. The apertures **56** are sized large enough so that no portion of the graft **20** resides in the blood flow path of the renal arteries **24**, and also so that renal arteries that are slightly axially offset from one another can be accommodated.

With specific reference to FIG. **2**, the graft **20** comprises a tubular graft body **60** internally supported by a stent **62**. The tubular graft body **60** may be formed of one or more pieces, typically of a biocompatible fabric such as polyester (e.g., polyterepthalate). Alternatively, the graft body **60** may be an extruded PTFE tube. In a particular preferred embodiment, the graft body **60** is one piece, with the apertures **56** formed by diametrically-opposed, generally oval-shaped windows **64** cut in the body and extending circumferentially around the body into proximity with one another. Two bridge segments **66** of the graft body **60** extend between the first and second tubular sections **50, 52** of the graft and separate the windows **64**. Preferably, the bridge segments **66** extend circumferentially around the graft body **60** a small arc in relation to the adjacent windows **64** so as to maximize the size of the blood flow apertures **56**. In one embodiment, the bridge segments **66** each circumferentially extends between about 1–90° around the graft body **60**, and more preferably each extends about 5–10°.

The blood flow apertures **56** are sized to enable alignment with side branches of varying sizes. Of course, the particular size is defined by the axial dimension and the circumferential arc of the windows **64**, which depends on the overall graft diameter and length. For instance, a graft that is designed for small arteries and small side branches will have a reduced diameter and reduced window size. Additionally, if the graft is intended to bridge only one side branch then only one window is required. In a preferred embodiment, for use in the abdominal aorta **22** to bridge the renal arteries **24**, the graft **20** has a diameter of between about 19 and 30 mm, and a length of between about 22 and 46 mm. The opposed windows **64** have an axial length of between about 6 and 20 mm, and extend circumferentially around the graft body **60** between about 90° and 189°. The renal arteries **24** typically have a diameter of between about 8–10 mm, and thus the windows **64** are desirably oversized to ensure open blood flow through the renals, and to accommodate offset or otherwise misaligned pairs of renals.

The stent **62** actually comprises a first stent portion within the first tubular section **50**, and a second stent portion within the second tubular section **52**. The first and second stent portions may be substantially similar in construction, or may be configured differently, as desired. Those of skill in the art will understand that a variety of different types of stents may be used to internally support a tubular graft body.

In a preferred embodiment, the stent **62** comprises a plurality of separate, spaced-apart wireforms **70**, each formed in an undulating, or sinusoidal pattern. Each of the wireforms **70** includes alternating peaks and valleys, with either the peaks or valleys being woven through the graft body. More specifically, as seen in FIG. **2**, there are three axially-spaced rows of wireforms **70** in the first tubular section **50**, and four axially-spaced rows of wireforms in the second tubular section **52**. Either the peaks or valleys of these rows of undulating wireforms are woven through slits **72** formed in the graft body **60**. In this manner, the wireforms **70** are prevented from migrating axially within the graft body **60** with respect to one another, and thus provide a fairly uniform inner support structure for the flexible graft body. As mentioned, each wireform is either radially self-expandable to the configuration shown, or is capable of plastic deformation when balloon-expanded. In either case, the stent **62** (comprising the array of wireforms **70**) compresses the graft body **62** against the inner wall of a tubular blood vessel to form a fluid seal therebetween. Moreover, certain materials and/or sleeve-like structures are available to enhance the seal between the exterior of the graft **20** and the vessel wall, and may be combined with the present invention.

A plurality of crimps **74** is visible on the exterior of the graft body **62**. The crimps **74** join free ends of each wireform **70**, which comprise one or more wire segments bent into the undulating pattern, and into the annular shape required. Though the crimps **74** are not sharp, they provide an irregular surface structure on the exterior of the graft **20**, and thus help secure the graft in position within the vessel.

The bridging member **54** seen in FIGS. **1** and **2** comprises a reinforcing strut **80** and the aforementioned bridge seg-

ments 66 of the graft body 60. The reinforcing strut 80 is a relatively rigid elongate member extending between the first and second tubular sections 50, 52 of the graft 20. In a preferred embodiment, the reinforcing strut 80 is a biocompatible metal (e.g., stainless-steel) strip or rod secured at each end to either the graft body 60 or the stent 62. If the ends of the reinforcing strut 80 are secured to the graft body 60 as shown, sutures are typically used to sew an eyelet, hook or other such feature (not shown) provided on each end of the reinforcing strut. If the ends of the reinforcing strut 80 are secured to the stent 62, crimps are preferably used between juxtaposed ends of the closest wireforms and the reinforcing strut. As shown, the reinforcing struts 80 are desirably located to the outside of the bridge segments 66, although the reverse configuration is contemplated as well.

The bridging members 54 serve to anchor one of the first and second tubular sections 50, 52 of the graft 20 with respect to the other, and desirably maintain the spacing between the tubular sections, while at the same time present very little in the way of structure that might occlude or otherwise interfere with the blood flow between the primary vessel 22 and the affected side branch 24. The bridging members 54 must have tensile strength to withstand migratory forces that may tend to separate the first and second tubular sections 50, 52. In an exemplary configuration, the upstream section 50 or 52 serves to anchor the downstream section by virtue of their connection with the bridging members 54. In addition, the bridging members 54 may be relatively rigid in the sense that they have column strength sufficient to prevent the tubular sections 50, 52 from migrating toward each other after implantation.

The bridging members 54 have a radial dimension that is approximately the same as the rest of the graft 20; that is, they do not project radially into or out from the side wall of the graft. The circumferential width of each bridging member 54 depends on the intended use for the graft 20. That is, if the graft 20 is to be used in the abdominal aorta 22 to bridge the renal arteries 24 as shown in the drawings, then there are two bridging members 54 diametrically spaced apart of relatively narrow circumferential width. In this way, the bridging members 54 each axially extend along the wall of the abdominal aorta 22 at 90° orientations from the openings to the renal arteries 24, and there is no chance of occluding blood flow between the abdominal aorta 22 and renal arteries 24. Alternatively, if there is only one side branch then there need only be one bridging member of relatively greater circumferential width than as shown. That is, the bridging member might extend 180° or more around the graft, with the corresponding window opening up the remaining portion. In general, as long as care is taken to orient the window(s) in registration with the side branch or branches, then the bridging member(s) will not occlude blood flow.

The embodiment of FIGS. 1 and 2 shows relatively rigid bridging members 54 that are constructed of, for example, wires. Alternatively, the bridging members 54 may be strips of biocompatible fabric or even sutures that provide tensile strength to prevent the downstream tubular section 52 from migrating with respect to the upstream section 50. In the illustrated example, the upstream section 50 anchors the graft 20, and in particular the downstream tubular section 52, with respect to the renal arteries 24. In this context, one or the other of the tubular sections 50, 52 may be designed to better anchor the graft 20 in the primary artery 22, and the other may perform another function, such as supplementing a damaged section of the artery so that another graft may be secured adjacent the side branch 24. Of course, however, both tubular sections 50, 52 can be constructed to have identical anchoring and vessel supporting characteristics if the graft 20 is used to repair a damaged length of the vessel that extends upstream and downstream of the side branch.

FIG. 3 illustrates an alternative graft 90 of the present invention having a first tubular section 92 separated from a second tubular section 94 across a gap 96 and connected across the gap by two bridging members 98. Again, the graft 90 comprises a graft body 100 and an internal stent 102. The graft body 100 may be a tubular biocompatible fabric, and in the illustrated embodiment is separated across the gap 96 into two tubular portions in the respective first and second tubular sections 92, 94. Because the facing edges of the two tubular portions of the graft body 100 are circular, the gap 96 is tubular. The stent 102 again comprises a plurality of spaced-apart annular wireforms, although it should be noted that the first tubular section 92 only has a single wireform 104.

The bridging members 98 are elongated planar bars or strips of relatively rigid material, such as stainless-steel or a suitable polymer connected directly to the stent 102 or to the graft body 100 in the first and second tubular sections 92, 94. Again, the bridging members 98 must have must have tensile strength to withstand migratory forces that may tend to separate the first and second tubular sections 92, 94 after implantation, while at the same time must not occlude or otherwise interfere with the blood flow between the primary vessel and the affected side branch or branches. Therefore, instead of being relatively rigid, the bridging members 98 may be strips of fabric, such as polyester, or sutures for that matter.

FIG. 4 illustrates an alternative graft 110 of the present invention having a first tubular section 112 separated from a second tubular section 114 across a gap 116 and connected across the gap by two bridging members 118. Again, the graft 110 comprises a graft body 120 and an internal stent 122. The graft body 120 may be a tubular biocompatible fabric, and in the illustrated embodiment is separated across the gap 116 into two tubular portions in the respective first and second tubular sections 112, 114. In this case the facing edges of the two tubular portions of the graft body 120 are uneven by virtue of a plurality of notches 123, and thus the gap 116 is uneven as well. The stent 122 again comprises a plurality of spaced-apart annular wireforms, with the first tubular section 112 having two wireforms and the second tubular section 114 having three.

The bridging members 118 each comprises lengths of wire either separate from the stent 122 or defined by extensions of one or the wireforms. If the bridging members 118 are separate from the stent 122, they are connected directly to the stent using a crimp 124, for example, or are connected indirectly via stitching 126 to the graft body 120. In an exemplary embodiment as illustrated, the bridging members 118 are connected via crimps 124 to free ends of the lowest wireform in the first tubular section 112 and sewn to the graft body 120 in the second tubular section 114.

FIG. 5 illustrates a still further exemplary graft 130 of the present invention having a first tubular section 132 separated from a second tubular section 134 across a gap 136 and connected across the gap by four (4) bridging members 138. Again, the graft 130 comprises a graft body 140 and a stent 142. The graft body 140 is desirably a tubular biocompatible fabric. The stent 142 again comprises a plurality of spaced-apart annular wireforms, with the first tubular section 132 having a single wireform 144 disposed on the exterior of the graft body 140. The external wireform 144 can either be

woven through slits in the graft body **140** as described above, or may be secured thereto with the use of suture thread.

The four bridging members **138** are distributed generally equidistantly around the circumference of the graft **130** and each comprises a narrow strip of fabric **146** and a reinforcement strut **148**. Again, the reinforcement struts **148** may be connected directly to the stent **142** using a crimp, for example, or are connected indirectly via stitching **149** to the graft body **140**. The use of four bridging members **138** may be desirable for stability when smaller branching vessels are involved so that the windows defined between the bridging members need not be as large as the previous embodiments.

FIGS. **6** and **7** illustrate a still further embodiment of a graft **150** of the present invention that defines a tubular structure having a first portion **152** and a second portion **154** separated from the first portion across a gap **156**. Two bridging members **158** extend generally axially between and couple the first and second portions **152, 154** to prevent their relative movement before during and after implantation. In this embodiment, the first portion **152** of the tubular structure is defined solely by a stent **160**, while the second portion **154** is defined by a stent **162** internally supporting a tubular graft body **164**.

The upper stent **160** comprises an annular wireform **166** having alternating peaks **168** and valleys **170** and contoured curvilinear segments **172** extending therebetween. The curvilinear segments **172** are shaped so as to nest together when the graft **150** is in a radially constricted state, so as to enable smaller compaction of the graft. The wireform **166** includes one or more segments connected into the annular shape by one or more crimps **174**. The lower stent **162** includes a plurality of axially-spaced undulating wireforms woven through the graft body **164**, as previously described.

The bridging members **158** each comprise lengths of wire either separate from the stents **160, 162** or defined by extensions of one or the wireforms. If the bridging members **158** are separate from the stents **160, 162**, they are connected directly to the upper stent **160** using a crimp **176**, and are connected directly to the lower stent **162** using a crimp or indirectly via stitching **178** to the graft body **164**. In an exemplary embodiment as illustrated, the bridging members **158** are connected via crimps **176** to free ends of the wireform **166** in the first portion **152** and sewn to the graft body **164** in the second portion **154**.

FIG. **6** shows the graft **150** in place within a primary vessel **180** (e.g., the abdominal aorta) and bridging two oppositely-directed vessel side branches **182** (e.g., the renal arteries). The first portion **152** is located to contact and support the primary vessel **180** on one side of the side branches **182**, while the second portion **154** is located to contact and support the primary vessel on the other side of the side branches. The gap **156** is positioned to permit blood flow between the primary vessel **180** and side branches **182**, as indicated by the flow arrows **184**. The bridging members **158** extend axially across the gap **156** against the wall of the primary vessel **180** at approximately 90° orientations from the side branches **182**. Another graft **186** (e.g., the trunk of a bifurcated graft) is seen positioned within the second portion **154**. In this way, the graft **186** is secured within the uniform and tubular second portion **154**, which in turn is anchored within the primary vessel **180** from its own contact with the vessel wall, and by virtue of its connection to the first portion **152** via the bridging members **158**. This system of supporting one graft with another permits graft positioning very close to the vessel side branches **182**, and is especially effective when the primary vessel is distended even very close to the side branches.

The axial dimensions of the various grafts disclosed herein may be selected to match the particular anatomical dimensions surrounding the affected side branch. That is, the grafts, including two tubular sections with an aperture or gap therebetween and bridging members connecting the sections, are sized so as to permit blood flow through the affected side branch and any adjacent side branches. For example, the graft **150** seen in FIGS. **6** and **7** is positioned so that the first portion **152** is above the renal arteries **182** and the second portion **154** is below the renals.

A more detailed depiction of the relative axial dimensions for the graft **150** and region of the abdominal artery **180** near the renals **182** is seen in FIGS. **8** and **9**. In addition to the renal arteries **182**, the openings for the superior mezzanteric artery **190** and the ciliac artery **192** are shown in FIG. **9**. These arteries typically project in the posterior direction, in contrast to the laterally-directed renals **182**, and are located close to but upstream of the renals. The distance from the lowest of the arteries **190** or **192** and the highest of the renals **182** is given as A, the distance from the upstream side of the highest of the renals **182** to the downstream side of the lowest of the renals is given as B, and the distance between the downstream side of the lowest of the renals to the end of the perceived healthy portion of the abdominal aorta **180** is given as C. In addition, the diameter of one of the renal arteries **182** is given as D. The axial dimensions of the graft **150** are given in FIG. **8** as: L for the overall for the tubular structure, L_1 for the first portion **152**, L_2 for the gap **156**, and L_3 for the second portion **154**.

In a preferred embodiment, L_2>D, and if the renal arteries **182** are offset, L_2>B. In addition, L_1 is preferably smaller than or equal to A, so that the first portion **152** does not occlude either of the arteries **190** or **192**. Finally, the length L_3 of the second portion **154** is desirably less than the length C of the healthy portion of the abdominal aorta **180**, but may be greater than C.

In a specific embodiment, for use in the abdominal aorta **180** to bridge the renal arteries **182**, the graft **150** has a diameter of between about 19 and 30 mm, and a length L of between about 22 and 46 mm. The renal arteries **182** typically have a diameter of between about 5–10 mm, and may be offset center-to-center up to 10 cm. Thus the gap **156** has an axial length L_2 of between about 6 and 20 mm, and is desirably oversized to ensure open blood flow through the renals and to accommodate offset or otherwise misaligned pairs of renals. The length L_1 for the first portion **152** is desirably about 6 mm, but may vary depending on need. The length C of the healthy portion of the abdominal aorta **180** should be at least 5 mm to enable the proper seal of the second portion **154** with the aorta, which is smaller than an endovascular repair would currently be indicated. The length L_3 of the second portion **154** is preferably at least 6 mm, more preferably about 10–20 mm. Of course, if the graft **20** is used to repair a longer section of vessel as a primary graft, the length L_3 of the second portion **154** can be longer than 20 mm, up to the currently accepted maximum length of straight tube vascular graft.

To ensure the proper size/configuration of graft, the surgeon first determines the anatomical landscape through the use of angioscopy; that is, by injecting a contrast media and visualizing flow through the affected vessels with an X-ray device. The dimensions noted in FIG. **9** can thus be obtained. A range of different sized grafts are preferably available, and the surgeon then selects the graft to match the anatomy in conformance with the above preferred guidelines.

During implantation, the surgeon can ensure proper placement and orientation of the grafts of the present invention with the use of radiopaque markers on the graft. For example, the stent structure, or portions thereof, could be radiopaque, or markers can be attached to the stent or graft body. In FIG. 7, for instance, the wireform **160** and the upper wireform in the stent **162** are desirably radiopaque so as to enable the surgeon to monitor the approximate axial borders of the gap **156**. Furthermore, the bridging members **158** or crimps **176** may be radiopaque to enable rotational orientation with respect to the respective side branch or branches.

A method of supporting a tubular primary graft in a primary blood vessel adjacent a vessel side branch, in accordance with the present invention can be illustrated with reference to the embodiment of FIG. **6**. First, the tubular graft **150** is implanted in the primary vessel **180** such that the first portion **160** contacts and supports the primary vessel on one side of a side branch **182**, in this case the two renal arteries, and the second portion **154** contacts and supports the primary vessel on the other side of the side branch. Implantation of the tubular graft **150** can be accomplished by releasing a self-expandable version of the graft from within a catheter sheath in the proper location, or positioning a balloon-expandable version of the graft and inflating a balloon within the interior of the graft. A primary graft **186** is then delivered in a radially constricted state to a position overlapping the end of the second portion **154** and radially expanded into contact therewith. Again, the primary graft **186** may be either self-expanding or balloon-expanding.

An alternative method comprises implanting the tubular graft **150** after the implantation of the primary graft **186**. That is, the second portion **154** of the tubular graft **150** is self- or balloon- expanded outward into contact with the primary graft **186**. Indeed, the primary graft **186** may be implanted for a significant period of time before the need for the supporting function of the tubular graft **150** is recognized.

As mentioned above, one tubular portion of the graft may perform an anchoring s function to maintain the position of the other portion that may or may not have the same anchoring characteristics. For instance, the graft portion upstream of the side branch may anchor the downstream portion, which in turn reinforces, supplements or seals with the primary vessel so as to enable placement of another graft in that location. The present invention has been described so far in terms of self- or balloon-expandable stents for anchoring, but those of skill in the art will recognize that there are other ways to anchor. For instance, staples, bent or corkscrew, are becoming more sophisticated and effective, and may be used for anchoring. For that matter, any means for anchoring one portion of the graft can be used.

While the foregoing is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Moreover, it will be obvious that certain other modifications may be practiced within the scope of the appended claims.

What is claimed is:

1. A vascular graft adapted for placement in a primary blood vessel and suited to bridge a vessel side branch, comprising:

a tubular structure defining an outer surface, a first portion of the outer surface being sized to contact and support the blood vessel on one side of the side branch, and a second portion of the outer surface being sized to contact and support the blood vessel on the other side of the side branch, the tubular structure defining an aperture for alignment with the side branch so as to permit blood flow between the blood vessel and the side branch;

wherein the first and second portions are separated across a gap and further including at least one bridging member traversing the gap and connecting the first and second portions so as to prevent relative axial separation of the two portions after implantation, the aperture being defined between the bridging member and the first and second portions.

2. The vascular graft of claim 1, including at least two bridging members and two apertures.

3. The vascular graft of claim 1, including four bridging members and four apertures.

4. The vascular graft of claim 1, wherein the bridging member includes a relatively rigid strut.

5. The vascular graft of claim 4, wherein the tubular structure comprises a flexible graft body and a support stent, wherein the strut is directly connected to the stent.

6. The vascular graft of claim 4, wherein the tubular structure comprises a flexible graft body and a support stent, wherein the strut is directly connected to the graft body.

7. A vascular graft adapted for placement in a primary blood vessel and suited to bridge a vessel side branch, comprising:

a tubular structure defining an outer surface, a first portion of the outer surface being sized to contact and support the blood vessel on one side of the side branch, and a second portion of the outer surface being sized to contact and support the blood vessel on the other side of the side branch, the tubular structure defining an aperture for alignment with the side branch so as to permit blood flow between the blood vessel and the side branch;

wherein the tubular structure comprises a flexible graft body and a support stent, and

wherein the flexible graft body is only provided in one of the first or second portions, the other portion being defined solely by the stent.

8. A vascular graft adapted for placement in a primary blood vessel and suited to bridge a vessel side branch, comprising:

a first tubular structure sized to contact and support the blood vessel on one side of the side branch;

a second tubular structure sized to contact and support the blood vessel on the other side of the side branch; and

four bridging members connecting the first and second tubular structures so as to define four apertures in the vascular graft sized for blood to flow through between the blood vessel and the side branch.

9. The vascular graft of claim 8 wherein the bridging member includes a relatively rigid strut.

10. The vascular graft of claim 9, wherein at least one of the first and second tubular structures comprises a flexible graft body and a support stent, wherein the strut is directly connected to the stent.

11. The vascular graft of claim 9, wherein at least one of the first and second tubular structures comprises a flexible graft body and a support stent, wherein the strut is directly connected to the graft body.

12. A vascular graft adapted for placement in a primary blood vessel and suited to bridge a vessel side branch, comprising:

a first tubular structure sized to contact and support the blood vessel on one side of the side branch;

a second tubular structure sized to contact and support the blood vessel on the other side of the side branch; and

at least one bridging member connecting the first and second tubular structures so as to define an aperture in the vascular graft sized for blood to flow through between the blood vessel and the side branch,

wherein at least one of the first and second tubular structures comprises a flexible graft body and a support stent, and

wherein the flexible graft body is only provided in one of the first or second tubular structures, the other tubular structure being defined solely by the stent.

13. A vascular graft system adapted for placement in a primary blood vessel and adjacent a vessel side branch, comprising:

a tubular support graft including a first tubular structure sized to contact and support the blood vessel on one side of the side branch, and a second tubular structure spaced from and connected to the first tubular structure and sized to contact and support the blood vessel on the other side of the side branch;

a tubular primary graft sized to co-axially couple with the first tubular structure; and

at least two bridging members connecting the first and second tubular structures so as to prevent relative axial separation of the two tubular structures after implantation, two apertures being defined between the bridging member and the first and second tubular structures of a sufficient size to permit blood flow though the vessel side branch.

14. The system of claim 13, wherein the primary vessel is the abdominal aorta, the vessel side branch comprises the renal arteries, and the tubular primary graft is a portion of a bifurcated graft.

15. A vascular graft system adapted for placement in a primary blood vessel and adjacent a vessel side branch, comprising:

a tubular support graft including a first tubular structure sized to contact and support the blood vessel on one side of the side branch, and a second tubular structure spaced from and connected to the first tubular structure and sized to contact and support the blood vessel on the other side of the side branch;

a tubular primary graft sized to co-axially couple with the first tubular structure; and

four bridging members connecting the first and second tubular structures so as to prevent relative axial separation of the two tubular structures after implantation, four apertures being defined between the bridging member and the first and second tubular structures of a sufficient size to permit blood flow though the vessel side branch.

16. A vascular graft system adapted for placement in a primary blood vessel and adjacent a vessel side branch, comprising:

a tubular support graft including a first tubular structure sized to contact and support the blood vessel on one side of the side branch, and a second tubular structure spaced from and connected to the first tubular structure and sized to contact and support the blood vessel on the other side of the side branch; and

a tubular primary graft sized to co-axially couple with the first tubular structure; and

at least one relatively rigid strut connecting the first and second tubular structures so as to prevent relative axial separation of the two tubular structures after implantation, an aperture being defined between the strut and the first and second tubular structures of a sufficient size to permit blood flow though the vessel side branch.

17. The system of claim 16, wherein at least one of the first and second tubular structures comprises a flexible graft body and a support stent, wherein the strut is directly connected to the stent.

18. The system of claim 16, wherein at least one of the first and second tubular structures comprises a flexible graft body and a support stent, wherein the strut is directly connected to the graft body.

19. A vascular graft system adapted for placement in the abdominal aorta and adjacent the renal arteries, comprising:

a tubular support graft including a first tubular structure sized to contact and support the abdominal aorta on one side of the renal arteries, and a second tubular structure spaced from and connected to the first tubular structure and sized to contact and support the abdominal aorta on the other side of the renal arteries; and

a tubular primary graft sized to co-axially couple with the first tubular structure

wherein at least one of the first and second tubular structures comprises a flexible graft body and a support stent, and

wherein the stent internally supports the one of the first and second tubular structures that is disposed infra-renally.

20. The system of claim 19, wherein the flexible graft body is only provided in the one of the first and second tubular structures that is disposed infra-renally, the other tubular structure disposed supra-renally being defined solely by the stent.

21. The system of claim 19, wherein the stent is self-expandable.

22. The system of claim 19, wherein the stent is balloon-expandable.

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